Development of a family-based treatment programme for childhood obesity using Intervention Mapping methods

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Objectives of the thesis

This thesis aimed to apply a systematic approach to intervention development and evaluation. It utilised research evidence from published evaluations of similar interventions and theory of behaviour change processes to underpin the intervention, whilst also incorporating end user input at all stages.

There were five objectives for the study:

1. To use Intervention Mapping to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of hypotheses related to improving health behaviours and health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

Abstract

Background

Reviews of primary research in developed countries and policy in the UK demonstrate there is a lack of evidence from well conducted RCTs on lifestyle interventions for childhood obesity (NICE 2006, SIGN 2003, Oude Luttikhuis et al. 2009).

Objectives

To develop, implement and evaluate the Y W8? family focused childhood obesity treatment programme using a randomized controlled trial.

Methods

The programme was developed using Bartholomew's Intervention Mapping framework. Using this stepped process a needs analysis was undertaken, a steering group formed, focus groups were completed in local schools and interviews took place with parents of obese children. The determinants identified by these processes were combined with relevant theories and information gathered through a literature review to develop the programme.

Y W8? is a 12 week course for families with children aged 8–13 years designed to assist with weight management. The RCT was designed as an individually randomised parallel-group trial with a waiting-list control group. Children in the intervention group (n=59) had their height, weight, self-reported physical activity levels, self-reported fruit and vegetable consumption and a measure of self-esteem recorded at pre- and post-assessment, whilst only height and weight was collected from the children in the control group (n=55).

Results

Twelve week (post course) results showed a significant difference in change in BMI z-score between the control and intervention group, mean difference = -0.12 (95% CI: 0.09 to 0.16, $F(1, 98) = 54.04$, $p < 0.0005$), with the control group increasing and the

intervention group decreasing their BMI z-score. Analysis showed this positive effect on weight status did not adversely affect linear growth. For the intervention group 81% of children completed the programme.

Implications

This RCT offers evidence to support the use of family-based treatment programmes in the treatment of childhood obesity and displays positive results in the short-term, at a lower cost than similar interventions. The thesis also demonstrates how a public health programme can be implemented and sustained in routine NHS practice.

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I would sincerely like to thank my supervisory team. My special thanks to Professor Louise Wallace and Dr. Douglas Howat for their support, motivation and encouragement throughout the duration of this project, (and it has been many years!). In the earlier stages Dr. Orla Dunn was my Director of Studies and gave me the belief to start this PhD and assurance that I would get to the end. All have been enthusiastic and incredibly helpful through each stage of this PhD.

Thanks to everyone at work who has encouraged and supported me through this. There are too many to mention, but I would like to single out Emma Cowen who has been the mainstay of Y W8? over the past 5 years and her enthusiasm and tenacity when working with children and families is motivating and inspiring.

My special thanks also to all the children, parents and their families who have taken part in the Y W8? Programme. I wish them all well in the future.

Thanks to Tom for his encouragement and support, (and knowledge of how to work computers and change page numbering), and for putting the children to bed when I have had a burning desire to get stuck into another chapter!

Finally, my thanks to anyone I have missed. Many people have played a part in the completion of this work it and it would be impossible to thank them all individually.

Declaration

Contribution of the author of the thesis

I declare that all the work within this thesis is my own work, and has not been submitted for any other degree at another university. During this project I was firstly employed as a 'Researcher in Childhood Obesity and Physical Activity' by Telford and Wrekin PCT, funded by Sport England and the Big Lottery. From February 2008 I was employed as 'Service Manager Nutrition and Obesity – Children' by Telford and Wrekin PCT with substantive funding. In April 2011 my role transferred to Shropshire Community Health NHS Trust. Due to the workload involved with the delivery of this project it is appropriate to describe what I did in some detail in the thesis declaration.

Development of programme and study design

I was responsible for organising and chairing the steering group for the programme. Using the experience of the attendees I was responsible for the development of the programme. I carried out the literature searches described in this thesis. I took the lead in the design of the qualitative methods and chose the methods of data collection and analysis. Dr. Orla Dunn, Professor Louise Wallace and Dr. Douglas Howat assisted me in making decisions regarding the design of the feasibility study and RCT.

Research Governance

Dr Orla Dunn and I completed the paperwork for the Research and Development approval for the focus groups from Telford and Wrekin PCT and Coventry University, and the COREC forms for the ethical approval of the studies from Coventry University and Shropshire NRES. I was responsible for completing the paperwork for Research and Development Approval for the studies from Telford and Wrekin PCT.

Delivery of the programme

A small team was used to the deliver the programme. Myself and Emma Cowen facilitated the family and parent only workshops, and Jo Burt and Michelle Garner delivered the physical activity sessions.

Data collection

I was responsible for the piloting of the various recruitment methods. Emma Cowen and I ensured all families whose data was used in the studies completed the relevant assent and consent forms. Emma Cowen and I carried out every aspect of the quantitative data collection at baseline, the end of the programme and at 9 month follow-up. I carried out the qualitative data collection, including preparation of the focus group and interview schedules. I identified the validated questionnaires used in the evaluation and developed the Healthy Family Behaviours Questionnaire and Y W8? Mentor session evaluation sheet used to assess fidelity to the programme. I also developed the Children and Parents Y W8? User evaluations to be completed at the end of the programme.

Data analysis and interpretation

I carried out all the statistical analysis and interpretation of the data described in this thesis. I took advice on statistical analysis and interpretation of the data from Professor Louise Wallace.

Write-up of the thesis

The writing is my own, but each chapter has been commented on by Professor Louise Wallace and Dr. Douglas Howat (supervisors). The structure of the thesis has evolved from discussions with these two supervisors.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

1.4.2 The Interactive Domain Model (IDM) of Best Practices in Health Promotion

The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

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As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

1.4.2 The Interactive Domain Model (IDM) of Best Practices in Health Promotion

The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

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approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

1.4.2 The Interactive Domain Model (IDM) of Best Practices in Health Promotion

The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

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The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

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The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

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1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

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The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

1.4.2 The Interactive Domain Model (IDM) of Best Practices in Health Promotion

The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

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Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

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1.2.1 The Telford context

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descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

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interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

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1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

1.4.2 The Interactive Domain Model (IDM) of Best Practices in Health Promotion

The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

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1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

1.4.2 The Interactive Domain Model (IDM) of Best Practices in Health Promotion

The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

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Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

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Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

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descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

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In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

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The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

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The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

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The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

1.4.2 The Interactive Domain Model (IDM) of Best Practices in Health Promotion

The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

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The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

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The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

1.4.2 The Interactive Domain Model (IDM) of Best Practices in Health Promotion

The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

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approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

1.4.2 The Interactive Domain Model (IDM) of Best Practices in Health Promotion

The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

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The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

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1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

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The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

1.4.2 The Interactive Domain Model (IDM) of Best Practices in Health Promotion

The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

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1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

1.4.2 The Interactive Domain Model (IDM) of Best Practices in Health Promotion

The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

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The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

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1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

1.4.2 The Interactive Domain Model (IDM) of Best Practices in Health Promotion

The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

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Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

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Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

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descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

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The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

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The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

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The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

1.4.2 The Interactive Domain Model (IDM) of Best Practices in Health Promotion

The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

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The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

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The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

1.4.2 The Interactive Domain Model (IDM) of Best Practices in Health Promotion

The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

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approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

1.4.2 The Interactive Domain Model (IDM) of Best Practices in Health Promotion

The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

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The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

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1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

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The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

1.4.2 The Interactive Domain Model (IDM) of Best Practices in Health Promotion

The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

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1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

1.4.2 The Interactive Domain Model (IDM) of Best Practices in Health Promotion

The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

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The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

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1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

1.4.2 The Interactive Domain Model (IDM) of Best Practices in Health Promotion

The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

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Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

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Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

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descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

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The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

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The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

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The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

1.4.2 The Interactive Domain Model (IDM) of Best Practices in Health Promotion

The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

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The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

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The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

1.4.2 The Interactive Domain Model (IDM) of Best Practices in Health Promotion

The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

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approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

1.4.2 The Interactive Domain Model (IDM) of Best Practices in Health Promotion

The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

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The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

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1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

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The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

1.4.2 The Interactive Domain Model (IDM) of Best Practices in Health Promotion

The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

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1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

1.4.2 The Interactive Domain Model (IDM) of Best Practices in Health Promotion

The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

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The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

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1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

1.4.2 The Interactive Domain Model (IDM) of Best Practices in Health Promotion

The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

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Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

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Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

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descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

1.3.2 Why was this important to the local area?

As described above, from 2003 childhood obesity was identified by some health professionals as a particular health concern in Telford. Local school nurses and paediatricians were contacting the local Health Improvement Service to report consultations with increasing numbers of overweight and obese children with no other clinical conditions that required treatment ('simple' obesity), and no programme to refer them to for support with their weight. The Telford Health Improvement Service was already running a weight management service for adults, (formerly known as Lifestyle Change but since renamed Why Weight? Plus), so there was local support for the team to use their knowledge and expertise in the field to offer a programme for children and their families also. In 2005 Telford and Wrekin PCT produced its first obesity strategy and action plan – *Why Weight Act Now 2005-2009* (Telford and Wrekin PCT 2005) and formed a multi-disciplinary obesity steering group. Prevention and treatment of obesity in children was a key focus of this action plan and initial research at this time showed there were no national childhood obesity programmes to refer to. In addition, whilst

other programmes were in their infancy, no other areas in the UK had developed local programmes to the extent that they had proved effective and could be replicated. Therefore, the development of a childhood obesity treatment programme in the local area became a priority.

1.4 What approach to use?

At the time of development there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (Scottish Intercollegiate Guideline Network (SIGN) 2010). Within obesity management a structured, evidence-based approach to intervention development and evaluation was recommended (SIGN 2010 and NICE 2006). However, in practice there was little information on how to select and apply theory when developing and evaluating complex interventions (Michie et al. 2005). Thus, the researcher needed to investigate and choose an approach that offered a systematic method of gathering evidence about the nature of the behaviour to be changed, the opportunity to select and apply theory, and the ability to evaluate the effectiveness of the intervention. In addition, the 'locally developed' nature of this research meant that it was planned that local people would be involved in designing the intervention and in aspects of the evaluation. Alongside this the intervention needed to be based on the capacity and resources available in the local community. Importantly, consideration needed to be given to the sustainability of the programme in the future.

The intervention protocol needed to be designed for usability by local practitioners, requiring little direction from the researcher, to ensure the programme could be developed in a timely manner with little additional cost. Similarly, the evaluation design was built on realist principles, firmly embedding the intervention in its context (Pawson and Tilley 1997). Pawson and Tilley's work on Realistic Evaluation is an approach grounded in realism. It asserts that both the material and social worlds are 'real' and can have real effects; and that it is possible to work towards a closer understanding of what causes change. For this research their work is relevant to the development, implementation and evaluation. During development they promote consulting with different stakeholders as they will have different information and understandings about how a programme might work. Regarding implementation they suggest the contexts in

which programmes operate make a difference to the outcomes they achieve. Programme contexts include social, economic and political structures, organisational context and programme participants and staffing. For evaluation, Pawson and Tilley argue programmes work by enabling participants to make different choices, although choice-making is always constrained by participants' previous experiences, beliefs and attitudes, opportunities and access to resources, and it is important to determine in which contexts programmes do and do not work.

A number of approaches were considered, with three approaches being examined closely; the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) protocol.

1.4.1 ATM approach for developing logic models

The ATM approach was developed within the tradition of programme planning and evaluation suited to large scale public health programmes (Renger and Titcomb 2002). The ATM was developed to improve the effectiveness of how programme logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas. They undertook twenty stakeholder interviews to determine key antecedent conditions affecting student's entry into health professions. A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. From the resulting list existing activities were modified and new activities were developed to address the prioritised antecedent conditions. For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech, but after following the ATM

approach speakers were given some suggestions to include which related to the prioritised antecedent conditions. Whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach does not direct users to map theories to the strategies to develop understanding and effectiveness further. In addition, the approach does not assist the user in considering the long-term sustainability and implementation of the programme. Both these factors were important for this research, hence, the ATM approach was not considered further.

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The Interactive Domain Model (IDM) is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). The framework has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007). Whilst offering evidence based research and community consultation in the early stages, the version of the framework available at the time it was required was unsuitable for use in this research. For example, the IDM Best Practices Manual (Kahan and Goodstadt 2005a) and IDM Best Practices Road Map for Coaches (Kahan and Goodstadt 2005b) were not available until after this intervention had commenced development. This would have meant a high level of direction would have been required from the methodology experts to be able to use the framework which would have been impractical due to financial and time constraints, so this approach was rejected from further consideration.

1.4.3 The Intervention Mapping (IM) protocol

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a

structured process for the development of theory- and evidence-based programmes. IM is an iterative process encompassing six key steps. Each step comprises a number of tasks creating intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design. Importantly for this research, the 'locally developed' aspect fitted well with IM as Step 1 of the protocol includes the formation of a steering group, conducting a needs assessment and an analysis of local community capacity and resources. Investigation of other interventions that had used this protocol demonstrated it was user-friendly, with useful information regarding working through each step and the expected outcomes freely available on the internet. Lastly, step 5 - specifying adoption and implementation plans, offered the researcher the opportunity to consider the sustainability of the programme in the future. Hence, the IM protocol was chosen for the development of this intervention.

1.4.4 Medical Research Council's (MRC) Developing and Evaluating Complex Interventions

This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

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The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 1 Introduction

1.1 Introduction

This chapter provides an introduction to this research by giving the background to the project including an introduction to the town of Telford. The rationale for the research is given including why it was decided to research this topic, why this project was important to the local area and how the introduction of Government policy at a national level drove the implementation of childhood obesity treatment programmes. The chapter continues by discussing the Intervention Mapping (IM) methodology used to develop the programme and gives the reader an understanding of why this approach was chosen over a number of alternatives. The aim and research objectives will be given, and an introduction is given to the Normalisation Process Theory (NPT) framework which informs planning for implementation and sustainability of the intervention in the current organisation, and other UK organisations. To conclude an outline of the chapters included in this thesis is given.

1.2 Background to the research

This thesis documents the development, delivery and evaluation of the Y W8? programme – a family-based childhood obesity treatment programme for children aged 8 to 13 years of age who are overweight or obese. The research began in 2005. Prior to this, in 2003, a need was identified by local health professionals for a childhood obesity treatment programme for those children with 'simple' obesity, i.e. no other conditions or co-morbidities. Research at the time showed there were very limited programmes of this nature being delivered in the United Kingdom (UK) and it became apparent that there was a need to develop a programme to be delivered in the local area (Summerbell et al. 2003 and NICE 2006).

Funding for the project was secured in 2005 through a bid made to Sport England and the Big Lottery as part of their 'Active England' programme. The research was conducted as a collaboration between the Applied Research Centre for Health and Lifestyle Interventions (ARC HLI) at Coventry University and the Health Improvement Department at Telford and Wrekin Primary Care Trust (PCT). For the first three years of

the research the author was employed as ‘Researcher in Childhood Obesity and Physical Activity’ within the Health Improvement Department at the PCT. From February 2008 the PCT agreed substantive funding to continue delivery of the Y W8? programme as part of the Health Improvement Service. In April 2011 the Health Improvement Department of Telford and Wrekin PCT moved into the Operations Directorate of Shropshire Community Health NHS Trust. This department is responsible for the ongoing delivery of the developed programme and is funded by commissioners in NHS Telford and Wrekin. With the abolition of PCTs and Strategic Health Authorities (SHA), from April 2013 the public health functions of the PCT will be transferred to the local authority of Telford and Wrekin. The local authority will convene a Health and Wellbeing board and the council will be responsible for driving improvement in, and closer working across, health and care services. The council will have a duty to commission services to improve the health of the population, and the commissioning of childhood obesity services will be included in this.

1.2.1 The Telford context

Telford is a fast growing new town in the county of Shropshire. It comprises 112 square miles in north-east Shropshire. The town was built in the 1960s and 1970s and comprises many old mining towns and villages. Originally many of the town’s residents came from the overspill of Wolverhampton and Birmingham. In the 1990s it had one of the fastest growing populations in England. It now has a population of 170000 which is forecast to grow to 196000 by 2026. Telford has a younger population, 20.1% are aged between 0 and 15 years, compared to 18.7% nationally. This has been driven by an increase in the birth rate and in-migration of families attracted by affordable housing (Francis 2012). Telford is in the top 30% most deprived local authorities in the West Midlands and in the top 40 most deprived nationally. The borough has fourteen areas that are in the top 10% most deprived nationally as well as relatively high levels of income deprivation with 15% of residents living in low income households. Compared with regional and national levels more of the workforce are employed in low-skilled occupations and receive below average wages. The proportion of children living in poverty in Telford is 24.1% compared with 20.9% in England (Francis 2011). Telford has a population that is 92.8% White, with the next largest ethnic group being those of Asian

descent comprising 3.3% of the population. This is less than both the West Midlands at 8.0% and England at 5.3% (Francis 2012).

1.3 Rationale for the research

1.3.1 Why research this topic?

When this research commenced in 2005 the prevalence of obesity in children in England was described as being at 'epidemic' proportions and continuing to rise (Jotangia et al. 2005). In the same year the International Obesity Task Force (IOTF) produced a briefing paper demonstrating the rapid acceleration of childhood overweight and obesity in European countries, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England (Lobstein, Rigby and Leach 2005). At this time the prevention and treatment of childhood obesity became a priority for the Government, and the public health White Paper *Choosing Health* set a Public Service Agreement (PSA) target: 'to halt, by 2010 the year-on-year rise in obesity among children under 11 in the context of a broader strategy to tackle obesity in the population as a whole' (Department of Health 2004a). In response to setting the target the Government made plans to achieve this which included the treatment of children who have become overweight or obese. The plans acknowledged evidence of what works in the prevention and treatment of childhood obesity was in short supply and needed to be developed. They suggested programmes would need to be evaluated to understand the impact they have on children who are overweight or obese (Audit Commission, Healthcare Commission and National Audit Office 2006).

In 2006 the National Institute for Health and Clinical Excellence (NICE) published guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). The guidance supported the implementation of the *Choosing Health* White Paper in England and the Governments' 2004 PSA target. This document highlighted the paucity of UK based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for research evaluating multi-component interventions to manage obesity in primary care and that

interventions should be undertaken in 'real world' everyday clinical and non-clinical settings.

Reviews of the literature at this time (Summerbell et al. 2003, McLean et al. 2003) also reported an inadequate evidence base from which to draw definitive conclusions regarding how to best manage and treat obesity in children, and a lack of UK based studies. Most of the studies offering evidence regarding the treatment of obese children using family-based models were from the United States of America (USA) and Israel. The evidence from these countries indicated that targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and including behavioural change techniques had proved successful (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Epstein et al. 1998, Golan and Crow 2004, Golan, Kaufman and Shahar 2006). Developing and implementing a childhood obesity treatment programme for use in the UK was both valuable and timely both to test the successful components identified by previous research conducted outside the UK, and to add to the debate on how the treatment of childhood obesity could be best conducted and implemented within the UK National Health Service (NHS).

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This research was informed by the updated Medical Research Council's (MRC) framework for developing and evaluating complex interventions (Craig et al. 2008). In this context complex interventions are defined as interventions with several interacting components. The framework encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The framework emphasises the need to gain an understanding of the context of the problem, and the need to optimise the intervention and evaluation by including a feasibility and piloting stage, prior to decisions about whether to proceed to a definitive randomised controlled trial (RCT).

The MRC guidelines supports the use of a protocol such as IM as the framework is made up of stages; development, feasibility/piloting, implementation and evaluation (Campbell et al. 2007), which reflects the six key steps in the IM protocol. Similarly to IM, the stages of the MRC guidelines are not necessarily linear or cyclical and may be used throughout the intervention when appropriate.

The guidelines recommend that during the development of the complex intervention researchers identify the evidence base by conducting, or referring to, a systematic review, and develop a theoretical understanding of the likely process of change. The guidelines advocate the use of new primary research such as interviews with stakeholders, and suggest this should be carried out during both the development and evaluation of interventions. Once developed the intervention should be piloted prior to a full scale trial to assess the feasibility of the study, to test procedures for their acceptability, to estimate recruitment and retention rates, to calculate sample sizes and to test the evaluation methods. It is suggested that a mixture of qualitative and quantitative methods are needed for the evaluation. If a full scale trial is appropriate, consideration should be given to the study design, and the guidance advises that randomisation should always be considered as it is the most robust method of preventing selection bias and affecting outcomes. Based on the theoretical understanding of the intervention, suitable outcome measures should be chosen, with the guidance recommending a single primary outcome and a small number of secondary outcomes. In addition, a process evaluation should be carried out to understand the processes of why an intervention has worked or not worked, to assess fidelity and the quality of implementation. Finally, the guidance recommends an assessment of cost-effectiveness should be made, if possible, as this makes the results far more useful for commissioners who are buying in services for their local area.

The guidelines also recommend researchers have an effective implementation strategy to ensure evidence is put into practice and disseminated to others. Successful implementation relies on practical effectiveness – does the intervention work in real world settings and can it be implemented in everyday practice? (Haynes 1999). This aspect is very important for this research as it is being implemented in routine service immediately. The MRC guidelines also suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention. To assist with this the intervention could be documented in a manual or information made available on a web site. It is unlikely that a full description would be given in a scientific paper, so providing a full description of the intervention and its components in a manual supports implementation and ensures it can be reproduced.

1.5 Introduction to the Normalisation Process Theory (NPT) framework

The Normalisation Process Theory (NPT) framework was used to explore the implementation and sustainability of the programme in the current organisation and the possible implementation in other UK organisations. The NPT (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations. The NPT framework comprises four constructs; coherence (the ways that people make sense of the work of implementing and integrating a complex intervention), cognitive participation (how they engage with it), collective action (how they enact it) and reflexive monitoring (how they appraise its effects). These constructs are processed through and enable the complex intervention to become embedded in routine practice, and part of the normal activities that the workforce delivers.

1.6 Research objectives

This project aimed to apply evidence- and theory-based intervention methods of weight management and lifestyle change to underpin the development of a treatment intervention for obese young people through a programme of information, family involvement and support. To achieve this aim five objectives were identified:

1. To use Intervention Mapping (IM) to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of theory derived hypotheses related to the mechanisms underlying improving health behaviours and the health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

This thesis will describe the research and development undertaken to design the weight management programme and the methods used to evaluate its feasibility and

implementation. The thesis will illustrate how the aim and objectives have been achieved and will demonstrate how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community, and address important local health concerns.

1.7 Outline of chapters

Chapter 2 sets the scene for this research by reviewing how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Publications are reviewed to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Since the year 2000 English Government reports, strategies and White Papers have sought to launch targets to foster action, to introduce a national child measurement programme and to feedback children's weight status to parents. Latterly, they have used advances in technology and various media to engage with families and encourage lifestyle changes. Whilst targets have been missed and reset, the problem of childhood obesity continues to grow and the best methods of tackling the issue are still unclear.

The importance of measuring children's weight status is explored in more depth in chapter 3. The chapter focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status and considers its advantages and disadvantages as a measure for childhood obesity. The best tools for measuring change in weight status are also considered with a view to deciding the primary outcome measure for the present study. The chapter continues by considering the different definitions of overweight and obesity in children used in both national and international guidelines, and describes the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. With recent evidence suggesting a levelling off of the epidemic in some geographical areas, consideration is given to the methods of data collection in the UK and how this data can be used to inform planning and development of appropriate programmes.

Chapter 4 provides an overview of the literature concerning the non-medical treatment of childhood obesity. Both an overview of the systematic reviews undertaken on the topic is given, and the original literature review undertaken during the development of the

programme is reported. These provide an understanding of the factors considered important to be included in the intervention during its development. The second part of the chapter gives a review of childhood obesity treatment programme RCTs conducted between 2007 and 2012. This review of current literature allows an insight into other applicable childhood obesity RCTs and gives an insight into their effectiveness. The implications of these studies on the design of the present intervention are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based, and the use of a control group.

The methodology used to develop the programme, Intervention Mapping (IM), is described in chapter 5. The chapter commences by considering a range of frameworks which were considered for the development of the programme and continues by describing why IM was chosen. The chapter describes the six step IM protocol and documents the processes that were undertaken at each step to gain an understanding of how theories and evidence gained from the literature review and user views were integrated and developed into the childhood obesity treatment programme - 'Y W8?'. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme. This process meets the first objective of this research.

Chapter 6 details the feasibility study of the 'Y W8?' childhood obesity treatment programme and achieves the second research objective. The feasibility study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention, and to provide information for planning and justification of an RCT. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of the evaluation indicated that an RCT would be a feasible next step and this is reported in chapter 7.

The Y W8? RCT, which meets study objectives 3 and 4, is documented in chapter 7. The RCT required a change in recruitment procedure of family's to the study. This RCT offers evidence to support the usability of family-based treatment programmes in the treatment of childhood obesity, and achieved positive results in the short-term.

Chapter 8 describes the strengths and limitations of the research and compares the outcomes of the Y W8? RCT to the results achieved by the other childhood obesity RCTs running in the UK. The results show the mean reduction in BMI z-score achieved on the Y W8? programme is comparable with, and better than some, other published evaluations. The chapter also provides an economic evaluation of childhood obesity treatment programmes being delivered in the West Midlands, which demonstrates that the Y W8? programme is a low-priced intervention when compared with other similar projects. The chapter concludes by considering the implications for future research and uses the NPT framework to explore how the programme could be sustained in the current organisation, and implemented in other UK organisations. This addresses objective 5 of the study.

Finally, chapter 9 reviews the aim and objectives of the research and documents the impact the programme has had on public health provision in the local area. The chapter reflects on the study's aim to be locally driven, incorporating the needs and views of local people, and using the resources and capacity of the local area. The chapter includes a discussion of the final conclusions of the research and details how the intervention differs from other childhood obesity treatment programmes being researched in the UK, offering a unique contribution to research in this field.

Chapter 2 Policy context in England

2.1 Introduction

This chapter demonstrates that the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Documents published since the year 2000 concerning childhood obesity in the UK, including Government reports, strategies and White Papers are discussed in chronological order to demonstrate how the efforts to reduce levels of childhood obesity have changed and developed. Measures include the setting and resetting of targets, the introduction of a national measurement programme, use of new types of media through the internet and giving local government funds and responsibility.

2.2 Setting the policy context for the present study

Almost four decades ago an editorial in *The Lancet* identified obesity as the most important nutritional disease in the affluent countries of the world and called for efforts to prevent obesity in childhood (Anon. 1974). Since then the worldwide prevalence of childhood obesity has risen to such an extent that it is now described as a 'global epidemic' (World Health Organisation (WHO) 2000) affecting both the developed and developing world (James et al. 2001). This epidemic has affected a wide age range, both genders, most ethnic groups and individuals of every socioeconomic status (Bundred, Kitchiner and Buchan 2001, Strauss and Pollack 2001). The IOTF produced a briefing paper in 2005 with a focus on children in European countries (Lobstein, Rigby and Leach 2005). They demonstrated the rapid acceleration of childhood overweight and obesity, and comparisons with Western Europe showed the rate of increase in obesity was the steepest in England.

2.3 Public health policy since 2000

2.3.1 Tackling Obesity in England (2001)

In 2001 the National Audit Office (NAO) put a focus on childhood obesity in their report *Tackling Obesity in England* (NAO 2001). This highlighted the increasing prevalence, the human cost and the financial cost of obesity. The annual report from the Chief

Medical Officer (CMO) in 2002 described the rising prevalence of childhood obesity as 'a health time bomb with the potential to explode over the next three decades into thousands of extra cases of heart disease, certain cancers…'. He added: 'Unless this time bomb is diffused the consequences for the population's health, the costs to the NHS and losses to the economy will be disastrous', and urged action across Government departments (CMO 2002: 44). With studies demonstrating childhood BMI being linked to adulthood BMI, children with a BMI in the unhealthy weight category are more likely to become obese adults (Wright et al. 2001, Power, Lake and Cole 1997). As there is good evidence to show that adult obesity is associated with a wide range of medical problems (Bray 2004, Wyatt, Winters and Dubbert 2006), the CMO was correct to be concerned about the rising incidence of childhood obesity.

2.3.2 Choosing health: Making healthier choices easier (2004)

In 2004 the Department of Health (DH) published their white paper *Choosing health: Making healthier choices easier* (DH 2004a). This paper brought together policy themes published over the previous ten years and documented the Government's intention to use a new approach in tackling the nation's health. This new approach involved empowering people to make the 'right' or 'healthy' choice and signalled an acceptance of the need to achieve a 'fully-engaged' public who 'actively take ownership of their own health' as recommended in the Wanless report (Wanless 2002). These first steps in establishing a comprehensive cross sector approach to tackling obesity included putting in place strategies, goals and guidelines which would have the effect of raising the general standard of public health. The paper highlighted the importance of improving the quality and provision of public services, personalising services and providing a wider range of better, locally delivered services. The shared priorities for action in this paper included improving diet and nutrition and increasing exercise levels as a mechanism for reducing obesity. Two supporting action plans; *Choosing a Better Diet: a food and health action plan* (DH 2005a) and *Choosing Activity: a physical activity action plan* (DH 2005b) were published which focussed further on the activities to be undertaken to reduce obesity.

Within *Choosing Health* the Government set a PSA target 'to halt the year on year rise in obesity among children under 11 by 2010, in the context of a broader strategy to tackle obesity in the population as a whole'. This target was jointly owned by three

Government Departments; the Department of Health (DH), the Department for Education and Skills (DfES) and the Department for Culture, Media and Sport (DCMS). This target, and the need to collect reliable data to measure progress against the target, signalled the beginning of the National Child Measurement Programme (NCMP).

Whilst the White Paper was welcomed for its commitment to action to improve health it contained few concrete proposals which had a direct impact on obesity levels (Raine, Walt and Basnett 2004, UKPHA 2005). For example, it has been argued that the policy's aim to encourage and enable people to make healthy choices was flawed (Hunter 2005). Many individuals cannot choose whether or not they have sufficient income to be able to eat healthy food, or cannot walk or cycle when pedestrian and cycle routes are neither safe nor pleasant. In addition, the self-regulatory action on food, nutrition and physical activity still lagged behind the comprehensive action taken by Government on smoking in public places. The White Paper focussed on individual action to improve health and ignored measures to introduce effective regulation of the food and marketing industry, school food and consumer friendly nutritional information on all processed foods. Added to this, the obesity strategy for England was not published until 2008 (Cross-Government Obesity Unit, DH and DCSF 2008), a four year lapse which wasted crucial time in beginning to tackle obesity across the whole population and meeting the PSA target (Commission for Healthcare Audit and Inspection 2008).

2.3.3 Tackling child obesity – First steps (2006)

In response to the PSA target, which was jointly owned by the NHS and Local Authorities, the Audit Commission, Healthcare Commission and the NAO produced a joint report, *Tackling Child Obesity – First Steps* (2006). The report assessed the risks, opportunities and barriers to achieving the target and made recommendations about how the delivery chain for delivering the target might be strengthened or made more efficient. The report highlighted the complexity of childhood obesity at both the individual and strategic level; 'tackling child obesity requires changes in the behaviour of individual children and their parents and of society in general, which reflects recent trends across most developing countries to greater fat and sugar consumption and reduced physical activity' (Audit Commission, Healthcare Commission and NAO 2006:

9). The report documented that the Government planned to achieve the PSA target by using a range of approaches aimed at both prevention and treatment. For example, encouraging and supporting healthy eating and physical activity, particularly in schools, targeting antenatal nutrition, media campaigns and treating those children who have become overweight or obese. The key findings were that a multifaceted approach was the most effective, including changes at an individual level focusing on children and their parents or carers, and changes in society as a whole. The report acknowledged evidence of what works was in short supply and accepted there was a shortage of data to determine whether the range of programmes and initiatives was sufficient to achieve the target. It suggested programmes would need 'tight policy guidance, coordination and assessment systems if they are to work together to achieve change' (Audit Commission, Healthcare Commission and NAO 2006: 11) and added, 'evaluation of these programmes will need to focus on how they impact on different children, especially those who are overweight or obese' (p.11). With regards to measuring progress towards the PSA target the report drew the reader's attention to the lack of trustworthy data upon which to base activities and results; 'without reliable baseline data, there is a risk that resources will be wasted in unproductive activity' (p.7). Details in the report clarified that data collected would be mapped against schools and used as the basis for school-level interventions and performance management. Hence, the NCMP was launched.

2.3.4 National Child Measurement Programme (NCMP)

The NCMP was piloted in 2005/06 and was, at the time, called the National Childhood Obesity Database. During the pilot year data collection was hampered by a number of practical difficulties which had a significant impact on data quality and limited the reliability of the results. Lessons learnt from the pilot improved systems for subsequent years and from 2006/07 PCTs were required to return results to the DH in September of every year. The introduction of the NCMP was not without controversy, and has been said to be lacking coordination and poorly articulated in terms of its intended application of surveillance or screening (Lake 2009).

As part of the NCMP children in reception year (aged 4-5 years) and year 6 (aged 10-11 years) have their height and weight recorded to assess overweight and obese levels. The aims of the NCMP are to inform local planning and delivery of services for

children, gather population-level data to allow analysis of trends in growth patterns and obesity, increase population and professional understanding of weight issues in children and to be a vehicle for engaging with children and families about healthy lifestyles and weight issues (Swanton 2008). From 2009 PCTs were expected to feedback the results of the measurements to parents or carers in the form of a letter (Cross-Government Obesity Unit 2009a), and proactively follow-up on children identified as being underweight, overweight or obese from 2010 (Cross-Government Obesity Unit 2010a). With parents being informed of their child's weight status there is a need to be able to offer support to parents with children in the overweight categories. It is not ethical or effective to 'screen' children for obesity if there are no effective programmes in place to offer to families; therefore it is imperative that evidence-based treatment programmes are offered at a local level. Hence, the development of this local programme was timely to be able to offer families with overweight and obese children the opportunity to engage with an evidence- and theory-based weight management intervention as planned in the research aim and objectives. Results from the NCMP at a national, regional and local level are reported in section 3.4.2.2 and give an understanding of how this data can be used at these levels to gather population-level surveillance data, to analyse trends in childhood obesity and to plan and implement programmes.

2.3.5 NICE Guidance (2006)

In 2006 the National Institute for Health and Clinical Excellence (NICE) issued the first national guidance on the prevention, identification, assessment and management of overweight and obesity in adults and children in England and Wales. The guidance supported the implementation of *Choosing Health* in England and the Government's 2004 PSA target. The guidance gave recommendations for health service providers and other audiences such as local authorities, schools and workplaces regarding stemming the rising prevalence of obesity, increasing the effectiveness of preventative interventions and improving primary care services for those who are already obese. Regarding combating childhood overweight and obesity it recommends that multi-component interventions are the treatment of choice, 'for example, including dietary modification, targeted advice, family involvement and goal setting' (p.20). In addition, it asserts that interventions should offer a supportive environment where participants are able to learn behaviour change strategies to address physical activity levels and eating

behaviour within their family and social settings. According to the guidance the aim of weight management programmes for children should be either weight maintenance or weight loss, and to encourage a family approach to weight management, parents of overweight or obese children should be encouraged to lose weight if they are also overweight or obese (NICE 2006). This family approach is a crucial aspect of the intervention being developed in this study and both children and parent's height and weight were measured and reported to evaluate the effectiveness of the programme.

Although the guidance is a useful starting point for developing weight management programmes it only provided a high-level account of what was already known, rather than providing a detailed account of what was needed to be included in a successful weight management programme. In addition, a more comprehensive plan including a programme of action that clearly identified short, medium and longer term actions at local, regional and national level would have been more useful for those already working in the field. Future documents supported the NICE guidance and shared evidence of best practice and information regarding the development of local strategies to tackle overweight and obesity in children.

2.3.6 Care Pathway for the management of overweight and obesity (2006)

In 2006 the *Care Pathway for the Management of Overweight and Obesity* was published (Reddy 2006). This supports the care pathway that the DH made a commitment to developing in *Choosing Health* and contains evidence-based guidance to help primary care health professionals identify and treat children who are overweight and obese. It complements the NICE guidelines stating that, 'A sensitive, empathic, non-judgemental approach should underpin all obesity-related interventions' (p.2). The *Care Pathway* focuses on the treatment of obesity and gives more detail than the NICE guidelines, offering advice on the assessment of a child's weight status, exploring family's readiness to change and management of a child's weight, with useful information regarding programme content on physical activity, healthy eating, behaviour change and parenting support. It also reinforces the goal for most children on weight management programmes is not to lose weight, but to maintain their weight or reduce their rate of weight gain, while their height increases.

2.3.7 Foresight report (2007)

In October 2007 the UK Government's Foresight programme launched a document forecasting the obesity issue (Government Office for Science 2007). The Foresight programme, alongside the Horizon Scanning Centre, uses science based methods to provide visions of the future. The document's aim was to 'produce a long-term vision of how we can deliver a sustainable response to obesity in the UK over the next 40 years' (Government Office for Science 2007: 5). The Foresight programme analysed 12 years of data from the Health Survey for England (HSE) and modelled trends and prevalence through to 2050 (HSE 2007). The report gave the following predictions about childhood overweight and obesity in England:

- If current (2007) trends continue among young people under the age of 20, the prevalence of obesity will grow from current levels (8% males, 10% females) to around 15% by 2025
- By 2050 approximately 25% of young people will be obese
- By 2025, obesity among 11-15 year olds will have increased by six percentage points for boys and 11 percentage points for girls
- Among children aged 6-10 years, by 2025 21% of boys and 14% of girls will be obese

The report also highlights the serious financial consequences of obesity for the NHS. Foresight estimates that by 2050 the cost to the NHS could be £9.7 billion and the cost to the wider economy could be £49.9 billion. The report related tackling obesity as 'a societal challenge, similar to climate change' (Government Office for Science 2007: 3), requiring a long-term commitment at every level; personal, family, community and national.

2.3.8 Lightening the load: Tackling overweight and obesity (2007)

In 2007 another document was released to support the NICE guidelines – *Lightening the load: Tackling overweight and obesity* (Swanton and Frost 2007). This publication provides a toolkit for PCTs and local authorities to use to select the most appropriate interventions to tackle overweight and obesity in their area. This comprehensive document provides a starting point for the development of local strategies to tackle

overweight and obesity in children and adults, and acts as a central point to signpost the reader to established material regarding the prevention and management of obesity in all age groups (Swanton and Frost 2007). This document and the toolkit were a valuable resource in the development of the intervention in the present research as they were published as the feasibility study was starting. The evidence presented, and information regarding other programmes considered best practice, allowed comparison with other interventions at an early stage of development. The information regarding development of local strategies was used during the adoption and sustainability phase of intervention planning. Further details are provided in chapter 8.

2.3.9 Healthy Weight, Healthy Lives (2008)

In September 2007 the Government announced a new ambition 'of being the first major country to reverse the rising tide of obesity and overweight in the population by ensuring that all individuals are able to maintain a healthy weight. Our initial focus is on children: by 2020 we will have reduced the proportion of overweight and obese children to 2000 levels' (HM Government 2007: 10). This new target replaced the initial PSA target set in 2004 and forms part of the Government's new target known as PSA 12 on child health and well-being. The Government acknowledged that the initial target set in 2004, whilst not being met, had been effective in stimulating action across the country (Cross-Government Obesity Unit, DH and DCSF 2008).

The plans to achieve this new target were introduced in the national obesity strategy, *Healthy Weight, Healthy Lives: A Cross-Government Strategy for England,* which was published in January 2008 (Cross-Government Obesity Unit, DH and DCSF 2008). The publication heralded a new chapter in efforts to tackle obesity with the Government giving a year-on-year commitment to build a society in which a healthy weight can be maintained. Figure 2.1 displays the contribution various programmes need to make in order to reach the 2020 target.

Pertinent to the current research was the evidence based method of promoting healthy weight in children described as 'Targeted support for at-risk families'. This includes prevention and treatment for families most at risk, indicating that programmes such as the intervention in this research have a small albeit recognisable part to play. In addition, the NCMP formed part of the work to implement the *Healthy Weight, Healthy*

Lives strategy (Cross-Government Obesity Unit, DH and DCSF 2008), and accountability for reaching the target was based on indicators of BMI in reception year and year 6. Feeding back children's BMI to parents and providing pro-active follow-up to those who are overweight and obese was planned to assist with the 'targeted support for at-risk families' method identified in figure 2.1.

Figure 2.1 Projected impact of various programmes on BMI in children in order to reach the 2020 target

Source: Department of Health analysis

Source: Healthy Weight, Healthy Lives (Cross-Government Obesity Unit, DH and DCSF 2008: 9)

Healthy Weight, Healthy Lives: Commissioning weight management services for children and young people identified a three-tier model for local care pathways (figure 2.2) (CSIP NW/Cross-Government Obesity Unit 2008). PCTs and their partners were required to develop these care pathways. The intervention developed in this research is a targeted weight management service which fits in at level 2.

Figure 2.2 Three-tiers of care pathway for weight management of young people from *Healthy Weight, Healthy Lives*

Source: *Healthy Weight, Healthy Lives: Commissioning weight management services for children and young people* (CSIP NW/Cross-Government Obesity Unit 2008: 50)

2.3.10 Standard Evaluation Framework (SEF) (2009)

As part of the *Healthy Weight, Healthy Lives* strategy the National Obesity Observatory (NOO) was established in December 2007 and received core funding from the DH in April 2008. The NOO publishes national and regional reports of the NCMP and undertakes analysis of various datasets. In 2009 the NOO published a standard evaluation framework (SEF) for weight management interventions which aimed to gather consistent type and quality of data, and improve the evidence concerning the effectiveness of weight management interventions. This simple tool provides a framework which 'provides a set of core measures that should be collected before,

during and after any weight management intervention, with supporting guidance both on evaluation and data collection methods' (Roberts, Cavill and Rutter 2009: 5). The aim of the SEF was to promote high quality, consistent evaluation of weight management interventions in order to increase the evidence base.

The DH West Midlands commissioned a regional evaluation of weight management programmes for children and families which audited each programme against the essential and desirable criteria included in the SEF (Upton et al. 2009). After the regional evaluation had been published Upton et al. (2010) discussed their experience of using the SEF and fed back on its usefulness, 'the SEF enabled an effective comparison across child weight management interventions, in addition to the identification of positive areas for development. If used appropriately, the SEF has the potential to serve as a thorough data collection tool and increase the evidence base of effective paediatric weight management interventions and methodologically sound evaluation' (Upton et al. 2010: 34). They did, however, provide some ideas where the SEF could be improved. This included additional factors such as self-esteem being classified as essential rather than desirable criteria to enable a holistic evaluation, and the desirable criteria being ranked as to their importance to enable further analysis of programmes.

2.3.11 Change 4 Life (2009)

Further work at a national level to achieve the PSA target documented in *Healthy Weight, Healthy Lives* is the *Change4Life* campaign. Launched in January 2009 *Change4Life* is a £75 million social marketing campaign designed to change the behaviours of English families that lead to excess weight by helping families to 'eat better, move more and live longer'. The initial campaign was targeted at families with children aged five to eleven (Cross-Government Obesity Unit 2009b). The campaign's aim is to create a social movement to support changes in attitude and behaviour related to diet and exercise. The marketing programme is complex involving several audiences, a number of key behaviours and a range of partners and stakeholders. The campaign uses a website, television advertising, questionnaires and marketing materials intended to engage with families and provide key messages concerning leading a healthier lifestyle (NHS 2009).

To plan and develop the campaign a review of the evidence for effective behaviour change was conducted focusing on healthy eating and activity behaviours (Jebb, Steer and Holmes 2007). In addition, a major programme of market research was undertaken including a quantitative segmentation of English families supplemented by qualitative research and focused work with black and minority ethnic (BME) communities (DH 2008). This enabled the team to identify those families whose current attitudes and behaviours indicated that their children were most at risk of excess weight gain, and to gain insight into why those families held those attitudes and behaved as they did.

A major evaluation programme is running alongside the campaign to ensure effectiveness. This programme includes; monitoring campaign exposure, investigating the impact on families and tracking the development of a social movement (Cross-Government Obesity Unit 2010b). The first evaluation published in 2010 reported that during the first year of activity *Change4Life* exceeded all the targets including; reach, awareness, logo recognition, sign-up and sustained interest. The *Change4Life* evaluation indicated that 30% of mothers with children aged two to eleven claim to have changed at least one thing in their children's diets and activity levels as a direct result of *Change4Life*. If the survey results are true nationally, this equates to over one million families (HM Government 2010a).

In 2010, when the Coalition Government came to power, they put a freeze on non-essential marketing expenditure which included a reduction in social marketing programmes and expenditure on advertising all but ceased. The freeze allowed an assessment of the impact of a loss of mass communication. For *Change4Life* there was a negative impact; calls to the information line fell by 90%, web visits reduced by two thirds and the number of people joining *Change4Life* fell by 80% (DH 2011a).

Shifting priorities within the new Government has resulted in a change in the funds available for *Change4Life*. The amount spent on *Change4Life* in 2009/10 was £25 million; this was reduced to £14 million in 2011/12. To supplement this contributions from the commercial sector have increased from £9 million in 2009/10 and £12 million in 2010/11, to £15 million in 2011/12. The previous Government was criticised for linking with corporate partnerships, particularly partnerships with companies whose products are linked to the causes of obesity such as PepsiCo, Coca-cola, Mars and

Nestle (The Lancet 2009). These partnerships were viewed as a mechanism by which companies could link with a 'health' brand whilst avoiding measures or legislation that would make a real difference; such as protecting children from junk food marketing, forcing companies to use the most effective nutritional labelling or driving the reformulation of food. It seemed that *Change4Life* had "sold out" to unhealthy brands because of the need to generate funds (Stuart 2011). These partnerships dilute the messages and can cause confusion as they send mixed messages to the general public. For example, PepsiCo sponsored the *Play4Life* campaign – does this send the message that if you do exercise it is acceptable to drink Pepsi and eat crisps? (The Lancet 2009). A common criticism levelled at the campaign is that *Change4Life* has not addressed the challenge that behaviours leading to obesity are entrenched in our society and legislation is needed to support the campaign (Watts 2009).

The new Government has justified its decision to link with corporate partners by the need to tap into the power of brand loyalties, and the fact that these companies have influence with the target audience (The Lancet 2009). Others support this by arguing that it is better to have companies engaged and supporting messages than in a position of opposition (Hancock 2009), and it will only be through the combined power of Government, commercial and non-commercial organisations that key health messages will reach and resonate with a huge range of people (Fletcher 2009).

The adverts and messages have also been criticised for being too simplistic for what is a complex problem (The Lancet 2009). For example, the campaign received negative publicity when Diabetes UK argued that certain adverts fostered the misconception that diabetes is caused by being overweight, which led to children with Type 1 diabetes being bullied. The charity was successful in getting the wording of the adverts changed. Another example demonstrating the danger of simplifying the message occurred when a Facebook group 'Gamers fight back' was set up in reaction to the *Change4Life* poster campaign showing a young boy playing on a games console with the words: 'Risk an early death, just do nothing'. The leader of the group claimed that the Government had found inconclusive evidence about the impact of technology on obesity and those planning *Change4Life* should have identified this threat to the success of their campaign (Sweney 2009).

Further criticism of *Change4Life* concerned the campaigns lack of collaboration with family's and their delay in the use of social media. Although the audience have been given information about a healthy lifestyle, with the emphasis on completion of a survey, receiving action packs and the website, the DH should have created a dialogue with families to engage with them in a two-way exchange. For example, social media could have been used more effectively to reach the audience in a proactive way. The Facebook group and Twitter profiles were not set up until six months into the campaign. A more effective approach could have seen planners utilising these platforms to gauge opinion about diet and exercise and this could have resulted in greater engagement with individuals. This could also have been used as the campaign developed as a good means of listening to, and relating to, the target audience and improving the impact (Mitchell 2009).

2.3.12 Healthy lives, Healthy people: our strategy for public health in England (2010)

In an effort to engage further with the public the Coalition Government issued the White Paper *Healthy Lives, Healthy People: our strategy for public health in England* at the end of 2010 (HM Government 2010b). This paper puts local communities at the heart of public health by changing the approach through which public health is administered. Local Government will receive funding to innovate and develop their own ways of improving public health in their area. Financial incentives will be rewarded for progress on improving health and reducing health inequalities. In this paper the Government committed to development of the *Change4Life* programme and the continuation of the NCMP to provide local areas with information about levels of overweight and obesity in children to inform planning and commissioning of local services (HM Government 2010b).

2.3.13 Health lives, Healthy people: a call to action on obesity in England (2011)

Following on from the White Paper (HM Government 2010b), in October 2011 the government published *Health lives, Healthy people: a call to action on obesity in England* (DH 2011b). This document sets out how action on obesity will be delivered as the move is made towards a new public health system. The report announced the Government's new ambition for 'a sustained downward trend in the level of excess weight in children by 2020' (DH 2011b: 6). Whilst the headlines reported the 'calorie

reduction challenge' of 'reducing the population's calorie intake by 5 billion calories (kcal) a day to help to close the gap between energy in and energy out' (DH 2011b: 8), the document outlined the importance of creating the right environment for individuals to make healthier choices. In recognition of the limited evidence on the effectiveness of weight management services the report highlighted the importance of 'practice-based evidence' and called for a 'more concerted effort … both to synthesize and disseminate emerging evidence about effectiveness and cost-effectiveness and to put in place rigorous evaluation of local interventions' (DH 2011b: 26). The main components in delivering the ambition included; empowering individuals, further opportunities for the food and drink industry to play their part, giving local government freedom to provide the lead role in driving health improvement at a local level and further development of the evidence base on effectiveness and cost-effectiveness and promotion of good practice in tackling overweight and obesity. Included in the detail of these components are feedback on children's weight status through the NCMP, tailored support for weight management in local communities and continued investment and development in the *Change4Life* programme.

Alongside this paper the Government published a 3 year social marketing strategy for *Change4Life* (Mitchell 2011). The strategy set out a number of changes aimed at expanding the campaign whilst using less public money. It included *Change4Life* expanding to 'be the marketing programme for all health-related behaviours for families with children aged under 11 and for middle aged adults' (Mitchell 2011: 2). The strategy also revealed other developments; an increase in digital investment such as increasing its Facebook presence, a programme to encourage people to try unfamiliar healthy foods and new physical activities, and promotion of the health benefits of physical activity including supporting the 2012 Olympic health legacy.

The new strategy received a mixed response from industry groups and health charities. For example, Terence Stephenson, president of the Royal College of Paediatrics and Child Health (RCPCH) criticised the strategy, 'the plan has no clear measures on how the food and drink industry will be made to be more responsible in their aggressive marketing of unhealthy food' (Boseley 2011). Which? Executive director Richard Lloyd said the Government's approach was 'woefully inadequate' stating 'the Government calls on people to cut down the calories they eat, but isn't giving them the tools to do so' (Boseley 2011). Others were disappointed in the 'woolly overarching ambitions'

which did not specify the actual percentage by which the Government plans to reduce overweight and obesity (MacMillan 2011). In contrast, the Food and Drink Federation (FDF) commented that it was pleased with the Government's 'holistic approach' to the obesity problem (FDF 2011).

2.4 Summary

This review of publications has demonstrated how the rising prevalence of obesity in children has resulted in a significant policy response from the Government in England. Efforts to combat childhood obesity have changed and developed over time. Initially the focus was on the increasing prevalence and the cost of obesity to the individual, the NHS and the wider economy. Subsequent papers reframed the issue and focussed on empowering individuals to make choices about their own health, improving the quality and provision of locally delivered services and highlighting the need for a cross sector approach using strategies, goals and targets. This signalled the introduction of the NCMP, the results of which highlighted the need for further action at national, regional and local level. Whilst having its critics and, at times, attracting negative press the NCMP has assisted in raising the profile of childhood obesity and provides local areas with a mechanism of engaging with parents about their children's weight.

Focussing on families became a theme after this with the publication of the NICE guidelines which recommended the use of multi-component interventions involving dietary modification, targeted advice and family involvement. Further publications continued this theme by highlighting the need for targeted support for at-risk families based on multi-component family-based interventions, often delivered in community settings. The *Change4Life* campaign has been the most recent commitment by both the previous and present Government to address the issue and engage with families using TV advertising, the internet and social networking. The campaign is not without criticism, including its links with corporate partners to obtain funding, and the Government's resistance to committing to legislative changes.

2013 brings new challenges with a new public health system being formed which will be based in local government giving local authorities freedom to play the lead role in driving health improvement at a local level (Local Government Association 2012). Alongside this new ambitions have been set, and further opportunities given, to the

food and drink industry to play their part. With these changes the Government appears committed to continuing the development of the evidence base on the effectiveness and cost-effectiveness of weight management interventions, and promotion of good practice in tackling childhood overweight and obesity.

Chapter 3 Measuring, defining and the prevalence of childhood obesity

3.1 Introduction

This chapter discusses measuring obesity in children and focuses on the use of body mass index (BMI) as a tool for assessing and monitoring children's weight status. The chapter also considers the different definitions of overweight and obesity in children used in both national and international guidelines. These topics are presented here as the choice of measurement of obesity is very important in the development and implementation of this intervention. In particular, the decision affects the budget and resources necessary for the programme, and the training requirements of the staff who will be delivering the intervention. The chapter continues by describing the current levels and trends in childhood obesity prevalence at an international, national, regional and local level. This data is of interest as at a national and regional level it highlights the high levels of childhood obesity in the UK. At a local level the data can be used to determine the number of children eligible for a weight management programme, and knowledge of the schools they attend assists in determining the localities in which to deliver programmes. The final part of this chapter focuses on future predictions of childhood obesity.

3.2 Measuring obesity in children

Overweight and obesity are terms used to describe increasing degrees of excess body fat which can lead to increasingly adverse effects on an individual's health and wellbeing (Swanton and Frost 2007). Accurately measuring levels of obesity in children is very important to ensure at an individual level the correct treatment option is offered, and at a population level services can be planned to target those requiring support. Studies have shown that parents (Jeffrey et al. 2005), mothers (Parkinson et al. 2011) and health care professionals (Smith, Gately and Rudolf 2008) underestimate children's weight and fail to categorise them correctly. For example, in a cross sectional study of 277 British families only 25% of parents with overweight children recognised that their child was overweight, and 33% of mothers and 57% of fathers described their child as 'about right' when they were obese (Jeffrey et al. 2005). Results from the HSE 2009 demonstrated that children aged 8-15 who were above a healthy weight for their height also failed to recognise their own weight status; with 75%

of boys and 41% of girls who were overweight, and 33% of boys and 22% of girls who were obese, indicating in the self-completion exercise that they were about the right weight (The NHS Information Centre 2009). These studies highlight the need for accurate measurements of adiposity rather than relying on visual cues or self-report.

A number of different methods are used to measure body fat in children and these have been reviewed in two papers (Wells and Fewtrell 2006, Sweeting 2007). Table 3.1 describes the main methods available to measure body fat and their advantages and limitations. Many of the methods shown are expensive and not commonly accessible in routine practice. An 'easy to use' proxy measurement is necessary for day-to-day practice in both clinical and community settings. As such, further discussion of these methods is beyond the scope of this thesis.

3.2.1 Using body mass index to measure obesity in children

Cole (1979) was the first to suggest the use of BMI in children and its use has been recommended in clinical guidelines for the NHS in England (NICE 2006) and in Scotland (SIGN 2003). It is recognised as the best simple anthropometric measure in monitoring population level obesity (Hall and Cole 2006). In addition, BMI has been identified as an effective and evidence based measure of childhood obesity providing the best simple means of defining obesity in children and adolescents (Reilly 2007). Power, Lake and Cole (1997) suggested that of equal importance is the simplicity of the measure, the cost, ease of use and acceptability to the subject. BMI has become widely adopted as a proxy measure of adiposity. Although it is not a measure of body composition per se (i.e. does not measure fat), it is a measure of weight in relation to height.

Measurement of BMI is non-invasive, safe, easy to use and because it is calculated from simple measurements of height and weight it is inexpensive (Daniels 2009). The equipment required to measure height and weight is simple to use, practical to move around to different locations and inexpensive compared to equipment required for other more complex measures. BMI has also been measured and reported around the world for some time. Therefore, published thresholds and growth references are available to which children's BMI can be compared, and comparisons can be made between populations over time (NOO 2009).

Table 3.1 Methods available to measure body fat

	Description	Advantages	Limitations
Simple methods			
Body mass index (BMI)	Weight (kg) / height^2 (m) – used as an index of weight in relation to height	Reference data available taking into account age and sex (expressed as SDS or *z*-score) Quick and simple Inexpensive Non-invasive Acceptable for day-to-day practice in both clinical and community settings Equipment is practical to move around	Not a measure of body composition i.e. does not distinguish between fat and lean mass For a given BMI in children there is a large variation in body fat percentage Lack of consensus concerning the cut-off points to define overweight and obesity in children
Waist circumference	Direct measure of waist circumference provides a simple measure of central obesity	Simple and quick Reference data available for nationally representative sample of UK children Inexpensive Central fatness is of a greater relevance to metabolic risk Easily portable	Not as accurate as measure of visceral fat Need to reveal waist area
Predictive methods			
Skinfold thickness measurements	Callipers are used to measure the amount of subcutaneous fat at a number of sites (peripheral and trunk areas)	Quick and simple Inexpensive Easily portable Raw values are reliable indices of regional fatness Can be converted into standard deviation scores (SDS) for longitudinal evaluations	In obese children accuracy and precision are poor Need to partially undress Prediction equations are not derived from the population understudy resulting in reduced accuracy Considerable training is required to take results accurately
Bioelectrical impedance analysis (BIA)	Measures resistance to flow of an electric current through the body to estimate body fat percentage	Simple and quick Non-invasive Equipment is portable Relatively inexpensive	Prediction equations utilise assumptions which make them useful only in the population from which the equations were derived Affected by hydration status

Table 3.1 Methods available to measure body fat (cont'd)

Density-based methods			
Hydrodensitometry (underwater weighing)	Weighs the individual while submerged in a large tank (having exhaled maximally) and also outside the tank	Often described as the 'gold standard'	Time-consuming Requires the individual to submerge themselves so unsuitable for children Disease reduces density of lean mass and therefore reduces accuracy Special equipment required – limited to research settings
Air displacement plethysmography (ADP) (BODPOD)	Measures the volume of air the individual displaces inside an enclose chamber	Suitable for children High level of accuracy	Special equipment required – limited to research settings Expensive
Scanning methods			
Magnetic resonance imaging (MRI) and Computerised tomography (CT)	Imaging technique that estimates the volume of adipose tissue	Allows estimation of regional body composition i.e. intra-abdominal adipose tissue	Special equipment required – limited to research settings Expensive Requires a relatively high radiation dose (CT)
Dual-energy x-ray absorptiometry (DEXA)	As bone, muscle and fat all absorb and transmit x-rays differently, patterns of x-ray absorption can be used to estimate the amounts and densities of tissues within the body	Quick Acceptable to children Assesses regional fat distribution as well as overall fat mass	Cannot differentiate directly between visceral and subcutaneous fat Exposure to low level radiation Problems with accuracy Lack of reference data Special equipment required – limited to research settings
Isotope dilution			
Deuterium dilution	Water labelled with deuterium is ingested and then saliva, urine or blood is analysed by mass spectrometry to measure total body water, allowing estimation of fat free mass	Simple to carry out Acceptable for all age groups Requires minimal subject co-operation	Special equipment required for analysis Delay in obtaining results Inaccurate if disease affects hydration status

Sources of information: NOO (2009), Wells and Fewtrell (2006), Sweeting (2007)

3.2.1.1 Limitations of using BMI in children

Despite the widespread use of the BMI it does have limitations in its ability to measure excess body fat in children. BMI does not distinguish between lean body mass and fat mass so is not a direct measure of adiposity (Daniels 2009). It also gives no indication of the distribution of body fat (Hall and Cole 2006). A lower BMI does not always equate to decreased adiposity, and individuals with higher lean body mass and lower fat mass may also be misclassified by using BMI as the measurement method. For example, physical activity may cause an individual to reduce their fat mass and increase their muscle mass. However, their BMI will stay the same if their height and weight have not changed despite their change in body composition (Hall and Cole 2006). This lack of change in BMI can be demotivating to individuals who are trying hard to make positive lifestyle changes but apparently not seeing the desired effect. This may be a reason for individuals failing to adhere to their treatment programme (Daniels 2009).

In addition, ethnic origin and puberty can alter the relationship between BMI and body fatness (NOO 2009). This has led to the belief that children could be misclassified or misdiagnosed. However, Reilly (2007) remarks that the evidence shows clearly that this kind of misclassification is rare, with almost all children with a high BMI for their age having excessive levels of fat. In an earlier paper the same author argues that the greatest potential for misclassification when using BMI is the opposite of this problem: BMI is not sensitive enough, missing children who have a relatively low BMI but have a high level of adiposity (Reilly 2006).

Another limitation is the lack of consensus concerning the cut-off points in the BMI distribution that should be used to define overweight and obesity in children and adolescents. Body composition in children varies with age and sex. Therefore, unlike adults, the value of BMI used to define overweight and obesity in children will vary with age and sex. Toschke, Kurth and von Kries (2008) commented that the different definitions in use by various surveys, clinical guidelines and policy will yield different prevalence rates of obesity and overweight which may be under or over-estimated (see section 3.2.2 for further information).

Percentiles specific to age and gender are used to select cut-off points to define overweight and obesity. In the UK BMI centile charts were derived from UK 1990 growth reference curves (Cole, Freeman and Preece 1995). These charts use UK reference data from 1978 to 1990 which have been fixed at 1990 so that trends in BMI over time are related to this reference point. However, as these charts were developed using data gathered before the rising prevalence of childhood obesity the percentile values do not reflect the current population status. When the charts were developed only 1% of the population would have had a BMI greater than the 99th percentile. This presents a problem as 'there is an increasingly large population of children and adolescents who have BMIs above the 99th percentile for whom no further risk stratification is possible when using percentiles' (Daniels 2009).

As with adults, ethnicity also causes an additional problem when using BMI to classify children's weight status. Diverse ethnic groups are associated with a range of different body shapes, and different distribution of fat storage (NOO 2011a). Research in adults has shown that for the same level of BMI, people of South Asian ethnicity appear to carry more fat, and people of African ethnicity less fat, than the general population. These findings may have led to an underestimation of obesity among South Asians and an overestimation among African groups (Harding et al. 2008). In adults a BMI of 25.0 – 29.9kg/m^2 is classified as overweight, and obese is classified as a BMI of greater than 30.0kg/m^2. The WHO investigated the BMI cut-off points and concluded that in the adult Asian population there is a high risk of Type 2 diabetes and cardiovascular disease when BMI is lower than the existing WHO cut-off for overweight (25kg/m^2). However, the various studies from different Asian populations do not indicate a clear BMI cut-off point for all Asians for overweight or obesity. The 'observed risk' documented by the report varied from 22 to 25kg/m^2 and 'high risk' from 26 to 31kg/m^2 (WHO expert consultation 2004). The South Asian Health Foundation in the UK has recommended a lower threshold of 23kg/m^2 for classification of overweight in adult British South Asians (Kumar et al. 2010). However, the NICE guidance continues to advise that, as there is no universal agreement, the same thresholds should be used to classify overweight and obesity in all ethnic groups in the UK (NICE 2006). In 2010 an expert group was convened to examine the classification of BMI for children. The group concluded that further research was required on the relationship of body shape, fat mass and ethnicity in children and the current definitions remain the most appropriate for use in the UK (Viner et al. 2010).

3.2.2 Defining obesity in children using BMI

Flynn et al. (2006) suggest the variability in growth rates and gender-specific variations in body composition throughout childhood and adolescence present significant challenges in providing a definition of childhood obesity. In addition, it is difficult to accurately estimate the prevalence of the problem due to variations in the definition of childhood obesity between clinical and epidemiological studies, and national and international recommendations. Interpretation of BMI values in children and adolescents therefore depends on comparisons with population reference data, using cut-off points in the BMI distribution (BMI percentiles). In the UK the most commonly used growth reference charts are the British 1990 Growth Reference charts (UK90) and the IOTF growth reference charts (NOO 2011b). For children aged four years and over in the UK, the Growth Reference Review Group, a working group convened by the RCPCH, recommended that the UK90 be used for population monitoring and clinical assessment (Wright et al. 2002). The UK90 BMI reference is available on printed growth charts published by the Child Growth Foundation (Cole, Freeman and Preece 1995), and calculated BMI is easily plotted on gender- and age-specific growth charts to give an individual a 'centile' result specific to their age and gender (Reilly 2007). However, as the next section discusses, confusion still remains about choosing appropriate cut-off points for defining a child as overweight or obese.

3.2.2.1 UK National BMI Percentile Classification

The UK National BMI percentile classification gives a BMI threshold for each age above which a child is considered overweight or obese. For public health purposes, compared to UK90 reference data, those children whose BMI is above the 85th percentile are classified as overweight, and those children whose BMI is above the 95th percentile are classified as obese (NOO 2009). The PSA 12 obesity target defines childhood obesity using this classification (HM Government 2007). NICE (2006) considered there was a lack of evidence to support specific cut-offs in children. However, for pragmatic purposes they recommend using the 91st and 98th percentile to define overweight and obesity respectively. This is supported by the DH (2006), the SIGN (2003) and the Scientific Advisory Committee on Nutrition and the Royal College of Paediatrics and Child Health Expert Group (SACN/RCPCH 2012). Reilly et al.

(2002) supported these cut-offs, reasoning that when using a BMI of more than the 91st percentile sensitivity is moderately high, (it diagnoses few obese children as lean), and specificity is high, (it diagnoses few lean children as obese). The NCMP uses the 85th and 95th thresholds for publishing prevalence data, and the 91st and 98th thresholds when providing feedback to parents (Department of Health Obesity Team 2011).

3.2.2.2 International Classification

The IOTF has published an alternative international classification for measuring childhood obesity (Cole et al. 2000, Cole et al. 2007). The results are based on combining BMI data collected from six countries, (UK, Brazil, Hong Kong, the Netherlands, Singapore and the United States), including 190000 subjects aged from 0 to 25 years. The group's classification links childhood and adult obesity and overweight standards using evidence of clear associations between the adult BMI cut-off values of 25kg/m^2 and 30kg/m^2 and health risk. However, Reilly (2007) commented that these international definitions are more conservative than the UK definitions and tend to under diagnose the prevalence of obesity, particularly in boys. Other limitations include concerns about its sensitivity, (ability to identify all obese children as obese), the limited sample size of the reference population and the lack of BMI cut-off points for underweight. In practice, the IOTF cut-offs are similar to the 91st and 98th centile cut-offs of the UK reference chart (NOO 2011b). The benefit of using this classification is that it allows international comparisons of levels of obesity in children to be made (NOO 2009).

3.3 Measuring change in BMI in children

Barlow et al. (2002) highlighted that with the introduction of weight management programmes for children there is a need to assess short-term (e.g. 6 months) weight change in growing children. In this research measuring change in weight status of the participant's is key to evaluating the effectiveness of the intervention. When planning the measures to use consideration needed to be given to the how quickly the measurement could be taken, how invasive it was, the cost, whether it could be taken in community settings and the acceptability of the measure to both the participant's and professionals. These considerations led to BMI being chosen as the measure, and then investigation took place regarding the best gauge of change in this measure. Cole

et al. (2005) described and investigated four different ways of measuring change in adiposity in growing children (box 3.1).

Box 3.1 Measuring change in BMI

- Change in BMI
- Change in percentage BMI (BMI %)
- Change in BMI *z*-score*
- Change in BMI centile

* *BMI z-score (or Standard Deviation score) reflects the number of SDs above or below the mean BMI. i.e. BMI z-score of 2 indicates the child is two standard deviations above the mean BMI for their age and sex.*
(Cole et al. 2005)

To identify which of these methods is optimal in measuring change they studied 135 Italian children aged 29 to 68 months and measured their BMI on three occasions over a 9 month period. The criterion used by the authors was that 'the measure's within-child short-term variation should be the same whatever the child's adiposity' (Cole et al. 2005: 420). The study found that change in BMI *z*-score and BMI centile varied according to the child's baseline level of adiposity, with more obese children showing less variability. Although BMI centile is useful when classifying children into overweight and obese categories, this study showed that it is poor at quantifying change because it is insensitive to change at the highest and lowest centiles. Although BMI *z*-score is the best measurement for classifying children's obesity status, due to the skewness of the BMI distribution with the upper centiles being further apart, a given change in BMI corresponds to a smaller change in BMI *z*-score at higher centiles. This makes it problematic in evaluating weight changes in obese children. The authors suggest that short-term (i.e. 9 months) changes in adiposity are best assessed by changes in raw BMI units or BMI % units, although they qualify this conclusion stating that the advantage of these measures over BMI *z*-score is small. Although the study underlined the importance of looking for an appropriate method to assess adiposity change when following children at risk of obesity (Power, Lake and Cole 1997), the authors recognised that before practical recommendations can be made their conclusions need testing with larger samples over different age ranges and periods of follow-up (Cole et al. 2005). Charts show that BMI increases with age from around the age of seven, so that as a child gets older the absolute values for BMI which define

overweight and obesity increase, thus standardisation for age (e.g. by *z*-score) is essential when examining changes. This is a problem with using BMI or BMI % to measure change as they are not adjusted for age and sex.

Daniels (2009) discussed the use of *z*-scores and, although recognising it was a good way to measure obesity status as there is no ceiling at the 99th centile, he commented that 'these measures are not widely used in clinical practice, and *z*-scores are more difficult for patients and families to understand without proper explanation' (p.S38). Despite this the SEF for obesity treatment interventions from the NOO supports the use of change in BMI *z*-score to measure the change in a child's BMI 'using the BMI z-score, any reductions in a child's BMI z-score will be consistent within each reference population, that is their age group and sex, regardless of their original BMI value'. (Roberts, Cavill and Rutter 2009: 39). In addition, BMI z-scores are useful for evaluating the effectiveness of a programme (Roberts, Cavill and Rutter 2009).

The use of the change in BMI *z*-score was explored further by Hunt et al. (2007), who studied 92 obese children aged 7 to 19 years attending hospital weight management clinics, and measured BMI at two time-points (median interval 0.83 years). Percentage fat was measured via BIA as their 'gold standard' for fat loss. The change in BMI *z*-score was superior to BMI, weight (kg) and weight *z*-score in predicting changes in percentage fat, although for a given change in BMI *z*-score the range of percentage fat loss was wide. A limitation of this study was its reliance on BIA as a 'gold standard' as this method is less accurate than hydrodensitometry and ADP (see table 3.1 for further information).

Hunt et al. (2007) stated that to be certain of fat loss that was clinically significant the change in BMI *z*-score had to be at least -0.5 over a period of up to 6 months, and at least -0.6 over a 6-12 month period. An analysis of 130 children aged 4-15 years from the Obeldick's treatment intervention in Germany (Reinehr and Andler 2004) sub-divided children into four groups according to their change in BMI *z*-score at 12 months. Improvements in cardio-vascular risk, as measured by blood pressure (BP), high-density lipoprotein (HDL) and low-density lipoprotein (LDL) cholesterol, triglycerides, and insulin resistance were only observed in Group IV where the BMI decreased by -0.5 *z*-score or more, whereas an increase in BMI *z*-score led to an

increase in insulin resistance. Both of these studies suggest a similar size of change in BMI z-score (-0.5) is clinically significant.

3.4 Prevalence of childhood obesity

Reported rates of the prevalence and trends in childhood obesity is, as discussed above, influenced by the definition used (Chinn and Rona 2002). However, regardless of the definition used there is overwhelming evidence that the prevalence of childhood and adolescent obesity has increased dramatically across the world in both developed and developing countries over a relatively short period of time (WHO 2003).

3.4.1 International prevalence and trends

Childhood obesity has been described as a global epidemic (Flynn et al. 2006) and the prevalence has escalated throughout the world over the two past decades (Lobstein, Baur and Uauy 2004, Wang and Lobstein 2006, WHO 2000). Using the IOTF standard definition of childhood overweight and obesity, the worldwide prevalence of both overweight and obesity in children aged 5-17 years is approximately 10%, and obesity alone is 2-3% (Lobstein, Baur and Uauy 2004). Within developed countries overweight tends to be more prevalent among socio-economically disadvantaged children (Shrewsbury and Wardle 2008), and children of higher socio-economic status in developing countries (Lobstein, Baur and Uauy 2004, Wang, Monteiro and Popkin 2002). Figure 3.1 displays the increasing prevalence of childhood overweight in selected developed countries around the world, particularly since the 1990's (Lobstein and Jackson-Leach 2007). Moreover, England shows a marked increase to 25% in 2001, and although the prevalence is not as high as in the USA, it is increasing faster.

Figure 3.1 Prevalence of children who are overweight in selected countries in the world from 1967 to 2005

(Source: Lobstein and Jackson-Leach 2007: 4)

Whilst there is unquestionable evidence of increases in prevalence in recent decades, evidence for a continuing rise is not universal. Rokholm, Baker and Sorenson (2010) investigated a possible levelling off of the obesity epidemic since 1999 in children (aged 2 to 12 years) and adolescents (aged 13 to 18 years) by conducting a systematic review of the literature. The results of their study supported an overall levelling off of levels of obesity in children from Australia, Japan, the USA and Europe, except in Germany where a slight increase was found in boys and girls. In Asia, a decrease in obesity prevalence was observed in Japanese boys and girls, whereas a continuously strong increase was evident in Chinese and Vietnamese children. For adolescents, stability in obesity prevalence was observed in Europe, with a decrease found in England and girls in Switzerland. Evidence shows a reduced increase in obesity in Australia, and stability in the USA. In adolescents in Asia, as for children, a decrease in the prevalence of obesity was observed in Japan, but a continuous increase was seen in China. The authors commented that 'although the leveling off is evident in many studies, there is yet no consistent indication of a reversal of the epidemic' (p. 843) .... 'we cannot rule out that the current stability is only a temporary phase that will be followed by another increase in the future' (p. 843). The authors highlighted that it is still important to continue with research into the causes, mechanisms and treatment of

obesity as although the findings of this review support a leveling off the prevalence is higher than ever before (Rokholm, Baker and Sorenson 2010).

Olds et al. (2011) brought together data from nine countries, (Australia, China, England, France, Netherlands, New Zealand, Sweden, Switzerland and USA), and analysed data from 467294 children aged 2-19 years. Their analysis shows a slowing plateau in Australia, China, England, France, New Zealand and USA, and a decline in the prevalence of childhood obesity and overweight in Netherlands, Swedish girls and Switzerland. The authors conclude that 'it is unclear whether the stabilization trends outlined in the countries in this paper presage a long-term change in the rates of childhood overweight and obesity, or whether it is a temporary lull, and overweight and obesity rates will soon begin to rise again' (p. 355). Similarly to Rokholm, Baker and Sorenson (2010), the authors stress that whilst rates appear to be stabilizing they are still unacceptably high and have significant implications for the health and well-being of children (Olds et al. 2011).

3.4.2 National prevalence and trends

In the UK the BMI centile charts developed by Cole, Freeman and Preece (1995) were the first such reference data for the UK. Taking a definition of ≥ 85th centile for overweight and ≥ 95th centile for obesity gave a prevalence rate in 1990 of 15% overweight and 5% obese at any given age. To obtain a true picture of changing prevalence and trends in UK childhood obesity it is important to compare studies to the UK 1990 BMI age and gender-specific population data (Prentice 1998, Jebb and Prentice 2001). Dramatic increases in the prevalence of childhood obesity in the UK were noted in the mid to late 1990s (Reilly and Dorosty 1999, Reilly, Dorosty and Emmett 1999, Chinn and Rona 2001, Bundred, Kitchiner and Buchan 2001). Indeed a report from the British Medical Association (BMA) in 2005 estimated that there were approximately one million obese children and adolescents under the age of 16 in the UK (definition of obesity not cited) (BMA 2005).

National data sources that report changes in the prevalence of childhood obesity over time in England include the HSE and, more recently, the NCMP. Children's BMI has been included in the HSE since 1995 and the NCMP commenced in 2005. For both

data sources the 85th and 95th BMI percentile cut-offs are used to define overweight and obesity in children, using the 1990 UK reference data.

3.4.2.1 Health Survey for England (HSE) results

Figure 3.2 shows the prevalence of overweight and obesity by gender for children aged 2 to 10 years.

Figure 3.2 Prevalence of overweight and obesity by gender for children aged 2 to 10 years from 1995 to 2007

Source: The NHS Information Centre, Lifestyle Statistics (2009b)

The overall trend has been for an increase in the prevalence of obesity amongst both boys and girls from around 10% in 1995 to 17% in 2005, although it appears to have levelled off in 2006 and 2007. A further 16.1% of boys and 12.2% of girls were overweight, making a total of 33% of boys and 29% of girls overweight or obese in 2005, although showing some subsequent decline (The NHS Information Centre, Lifestyle Statistics 2009b).

Jotangia et al. (2005) further analysed the data from the HSE from 1995 to 2003 for 2 to 10 year olds by splitting the results into four sub-groups: 2-3, 4-5, 6-7 and 8-10 year olds. Figures 3.3 and 3.4 display these results.

Figure 3.3 Prevalence of obesity among children from 1995 to 2003 by age group

Source: Jotangia et al. (2005)

Figure 3.4 Prevalence of overweight (including obesity) among children from 1995 to 2003 by age group

Source: Jotangia et al. (2005)

This analysis showed that the increase in the prevalence of obesity was statistically significant only for the 8-10 year old group from 11.2% in 1995 to 16.5% in 2003 ($p<0.05$). There was a similar pattern when the overweight (including obesity) data was analysed. Across most age groups the prevalence increased, but these increases were significantly greatest amongst the two older age groups, 6-7 and 8-10 years. This gives support for the need for obesity treatment programmes targeting these age groups, and justifies the choice to deliver the intervention developed in this research to children aged eight to thirteen years of age.

Figure 3.5 shows the prevalence of overweight and obesity by gender for children aged 11 to 15 years of age from 1995 to 2007.

Figure 3.5 Prevalence of overweight and obesity by gender for children aged 11 to 15 years from 1995 to 2007

Source: The NHS Information Centre, Lifestyle Statistics (2009b)

The graph displays a similar upward trend in obesity in adolescents aged 11-15 years from 1995 to 2004 in the HSE, although there appears to be some reduction in the prevalence from 2005 (The NHS Information Centre, Lifestyle Statistics 2009b). The latest figures in 2007 showed that 17.6% of boys and 19% of girls aged 11-15 years

were defined as obese, with 32.9% and 33.8% defined as overweight (including obese), respectively.

3.4.2.2 National Child Measurement Programme (NCMP) results

Every year, as part of the NCMP, all primary school children in reception year (aged 4-5 years) and year 6 (aged 10-11 years) have their height and weight recorded to assess underweight, overweight and obese levels in England. The results are used to inform local planning and delivery of services for children and to gather population-level surveillance data to allow analysis of trends in growth patterns and obesity (Swanton 2008). Further information on the development and aims of the NCMP are given in section 2.3.4. The first measures for the NCMP were collected in 2005/06 and seven years of data have now been collected and analysed. The first year of data collection resulted in a low national response rate of 48%, with anecdotal evidence suggesting a high number of overweight children were withdrawn from the survey by their parents (Crowther et al. 2007). Thus, the results for 2005/06 are thought to 'significantly underestimate' the prevalence of childhood obesity and therefore will not be presented here. Since 2005/06 the sample sizes have increased every year (see table 3.2).

Table 3.2 Sample size and participation rates of the NCMP from 2005/06 to 2011/12

Year	Sample size	Participation rate
2005/06	Not given	48%
2006/07	876416	81%
2007/08	973073	87%
2008/09	1003849	91%
2009/10	1026366	92%
2010/11	1036608	94%
2011/12	1056780	93%

Sources: The Information Centre (2008a), The Information Centre (2008b), The NHS Information Centre, Lifestyle Statistics (2009a), The NHS Information Centre, Lifestyle Statistics (2010), The NHS Information Centre, Lifestyle Statistics (2011), The Health and Social Care Information Centre, Lifestyle Statistics (2012)

This represents a large data set providing unparalleled information regarding the weight status of school children in England. Since the NCMP commenced the overall participation rate has increased from 81% in 2006/07, 86.5% in 2007/08, 91.1% in 2008/09, 92.1% in 2009/10 to 93.8% in 2010/11 (Croft 2010, The NHS Information Centre, Lifestyle Statistics (2010), The NHS Information Centre, Lifestyle Statistics (2011)). It is worth noting that 2012/13 will be the first dataset where children measured in reception year will be measured as year 6 pupils. This, and then future years, will give a good indication of how the prevalence within the same cohort changes over the seven years of their primary education.

Table 3.3 displays the NCMP results from 2006/07 to 2011/12 for both reception year (aged 4-5 years) and year 6 (aged 10-11 years) children.

Table 3.3 Prevalence of overweight and obesity for reception year and year 6 children from 2006/07 to 2011/12 from the NCMP

	Overweight				Obese			
	Reception year		Year 6		Reception year		Year 6	
	Prevalence	95% CI ±	Prevalence	95% CI ±	Prevalence	95% CI ±	Prevalence	95% CI ±
2006/07	13.0	0.1	14.2	0.1	9.9	0.1	17.5	0.1
2007/08	13.0	0.1	14.3	0.1	9.6	0.1	18.3	0.1
2008/09	13.2	0.1	14.3	0.1	9.6	0.1	18.3	0.1
2009/10	13.3	0.1	14.6	0.1	9.8	0.1	18.7	0.1
2010/11	13.2	0.1	14.4	0.1	9.4	0.1	19.0	0.1
2011/12	13.1	0.1	14.7	0.1	9.5	0.1	19.2	0.1

Sources: The Information Centre (2008a), The Information Centre (2008b), The NHS Information Centre, Lifestyle Statistics (2009a), The NHS Information Centre, Lifestyle Statistics (2010), The NHS Information Centre, Lifestyle Statistics (2011), The Health and Social Care Information Centre, Lifestyle Statistics (2012)

The results show an apparent increase in the levels of obesity in year 6 children. However, regression analysis showed that 'for Year 6, PCTs with lower participation

rates also had lower levels of obesity prevalence than those with a higher participation rate. It also showed PCTs whose participation rate increased the most from 2006/07 tended to have greater increases in recorded obesity prevalence' (The NHS Information Centre, Lifestyle Statistics 2010: 18). This finding suggests that obese children were more likely to opt out of being measured and a lower participation rate tends to result in an underestimation of prevalence of obesity in year 6 children. For reception year children, participation rate was shown to have little or no effect on prevalence of obesity. What is also worth noting is that the prevalence of obesity is significantly higher for year 6 children compared with reception year children for all years, and the prevalence of obesity is significantly higher in boys than girls in both age groups.

The latest NCMP report from the NOO (NOO 2013) analysed the NCMP data to examine the changes in children's body mass index that have taken place since 2006/07. The report found evidence of a downward trend in the prevalence of obesity in boys in reception year. For reception year girls there was no statistically significant trend in the prevalence of obesity. For both boys and girls in year 6 there was a significant upward trend in obesity prevalence between 2007/08 and 2011/12, and there was an increase in mean BMI across the whole population. The analysis showed no statistically significant difference between the rate of increase for boys and girls in year 6.

3.4.2.2.1 Comparison of NCMP and HSE results

Since 2006 the NCMP results have been compared with the results of the HSE for those aged 4 and 5 and those aged 10 and 11. For the year 2006/07, apart from obese boys in reception, the prevalence rates were not statistically different between the two studies. The obesity prevalence estimate for boys in reception year was significantly higher in the HSE (The Information Centre 2008a). When the results for 2007/08 were compared the estimates for the proportion of reception year girls who were obese appeared higher from the HSE than the NCMP. There were no other significant differences revealed for the proportions of boys and girls of either age group for both overweight or obesity. In 2008/09 there were no significant differences for overweight or obesity in reception year or year 6 (The Health and Social Care Information Centre 2009). The HSE sample size in 2009 was too small compared with

the NCMP sample size to make reliable comparisons (The NHS Information Centre, Lifestyle Statistics 2010).

The surveys both use the 85th and 95th centiles from the UK reference population as cut-offs for overweight and obesity. A clear difference, however, is the sample size used by the two programmes. The HSE figures are based on a sample of children, whereas the NCMP is a census of all eligible children. Thus, the HSE sample size is very small compared the NCMP. Table 3.4 displays the sample size for both surveys from 2006 to 2010.

Table 3.4 Sample size for HSE and NCMP from 2006 to 2010

	HSE		NCMP	
	Reception year	Year 6	Reception year	Year 6
2006 (06/07)	785	908	435927	440489
2007 (07/08)	953	841	477652	495421
2008 (08/09)	829	974	506169	497680
2009 (09/10)	807 (in total)		526499	499869
2010 (10/11)	687	699	541255	495353

Sources: The Information Centre (2008a), The Health and Social Care Information Centre (2009), The Health and Social Care Information Centre (2011), Dinsdale, Ridler and Rutter (2012)

As the NCMP is a nationwide census of children it is possible to analyse the data by geographical location, and results can even be provided for individual schools (The Information Centre 2008a). This is an advantage of the NCMP over the HSE and means the NCMP data can be used to plan services and monitor progress against targets at a local level. An advantage of the HSE is that it has been collecting data since 1995 and so it can be used to monitor progress against the national target. Both of these surveys indicate that targeting of primary school children with weight management interventions is a priority. The HSE showed a significant rise in obesity amongst children aged 8-10 years of age from 1995 to 2003 (Jotangia et al. 2005). Furthermore, results from the NCMP since it commenced have shown that the

prevalence of obesity is significantly higher for pupils in year 6 (10 and 11 years) compared with those in reception year (4 and 5 years) (The Information Centre 2008a, The Information Centre 2008b, The NHS Information Centre, Lifestyle Statistics 2009a, The NHS Information Centre, Lifestyle Statistics 2010, The Health and Social Care Information Centre, Lifestyle Statistics 2012). In addition, obesity prevalence in reception year children may be decreasing among boys, but there is no strong evidence of any change for girls. For year 6 children there is a pattern of increasing prevalence for both boys and girls (Dinsdale, Ridler and Rutter 2012).

3.4.3 Regional prevalence and trends

Telford is in the West Midlands regional strategic SHA. The NCMP publishes data for each SHA to allow analyses of childhood obesity at a regional level. Figure 3.6 shows the NCMP data for each SHA from 2011/12 for year 6 children. The data for the West Midlands SHA is marked by an arrow. The result for England is also shown for information.

Figure 3.6 NCMP data for each SHA from 2011/12 for year 6 children

Source: The Health and Social Care Information Centre, Lifestyle Statistics (2012)

The results show that the West Midlands SHA (36.2%) has the third highest prevalence of overweight and obesity, behind London SHA (37.5%) and the North East SHA (37.0%) (The Health and Social Care Information Centre, Lifestyle Statistics (2012). This prevalence is above the England average of 33.9%. The lowest prevalence is found in the South East Coast SHA (30.8%) and the South Central SHA (30.8%).

3.4.4 Local prevalence and trends

Table 3.5 displays the prevalence of overweight and obesity for reception year and year 6 children from 2006/07 to 2011/12 for Telford and Wrekin PCT.

Table 3.5 Prevalence of overweight and obesity for reception year and year 6 children from 2006/07 to 2011/12 for Telford and Wrekin PCT

	Overweight				Obese			
	Reception year		Year 6		Reception year		Year 6	
	Prevalence	95% CI ±	Prevalence	95% CI ±	Prevalence	95% CI ±	Prevalence	95% CI ±
2006/07	17.0	1.9	16.0	1.7	12.5	1.6	19.0	1.9
2007/08	18.2	1.9	15.7	1.8	11.9	1.6	18.6	1.9
2008/09	16.7	1.7	15.3	1.7	11.7	1.5	18.8	1.8
2009/10	15.3	1.7	14.8	1.7	10.6	1.5	20.1	2.0
2010/11	14.5	1.8	14.8	1.7	10.4	1.5	18.7	1.9
2011/12	13.2	1.6	15.2	1.7	10.7	1.5	20.6	2.0

Sources: The Information Centre (2008a), The Information Centre (2008b), The NHS Information Centre, Lifestyle Statistics (2009a), The NHS Information Centre, Lifestyle Statistics (2010), The NHS Information Centre, Lifestyle Statistics (2011), The Health and Social Care Information Centre, Lifestyle Statistics (2012)

In Telford in reception year the prevalence of overweight and obesity appears to have steadily decreased over the duration of the programme. For children in year 6 the prevalence of overweight has also generally decreased whilst the prevalence of obesity has fluctuated. In 2011/12 levels of obesity in year 6 were at there highest since the NCMP started.

The local NCMP data from 2011/12 for all PCTs in the West Midlands SHA is shown in figures 3.7 (reception year) and 3.8 (year 6). The results for England and the West Midlands region are also shown for information. The data for Telford and Wrekin PCT is marked by an arrow.

Figure 3.7 Prevalence of obesity and overweight for reception year children for 2011/12 for local PCTs in the West Midlands SHA

Source: The Health and Social Care Information Centre, Lifestyle Statistics (2012)

Figure 3.8 Prevalence of obesity and overweight for year 6 children for 2011/12 for local PCTs in the West Midlands SHA

Source: The Health and Social Care Information Centre, Lifestyle Statistics (2012)

Figure 3.7 shows that when compared with the seventeen PCTs in the SHA Telford and Wrekin PCT ranks 8th highest (23.9%) for prevalence of overweight and obesity in reception year children. This compares with an average prevalence of 23.5% in the West Midlands and 22.6% in England. For year 6 children figure 3.8 shows that Telford and Wrekin PCT ranks 9th highest for prevalence of overweight and obesity (35.7%). This compares with an average prevalence of 36.2% in the West Midlands and 33.9% in England.

The public health annual report for Telford and Wrekin (Telford and Wrekin Council, NHS Telford and Wrekin 2011) presented the results from the NCMP for 2008/09 and converted the percentage prevalence into actual numbers of children. The report also analysed the data in relation to deprivation. The report documented;

- For reception year children 11.7% of boys (106 boys), and 11.7% of girls (100 girls), are obese. This level of obesity is significantly worse than the national average for England (9.6%)

- A significant proportion (44%) of 4-5 year olds who are classified as obese live in the most deprived communities of Telford and Wrekin
- 16.7% of reception year children are overweight - 16.9% of boys and 16.5% of girls (158 boys and 135 girls). This level of overweight is statistically significantly worse than the national average for England (13.2%)
- In year 6, 18.8% of children are obese, 19.9% of boys and 17.5% of girls (186 boys and 143 girls). This is not statistically different from the English average (18.3%)
- Almost half (49.5%) of 10-11 year olds who are obese live in the most deprived 40% of local communities
- In year 6, 15.3% of children are overweight, 14.8% of boys and 15.9% of girls (138 boys and 130 girls).

3.5 Future predictions

The Foresight report, *Tackling Obesities: Future Choices* (Butland et al. 2007) included predictions for the future prevalence of childhood obesity (further details are given in section 2.3.7). The Foresight programme analysed 12 years of data from the HSE and modelled trends and prevalence through to 2050. The evidence from the modelling suggests that trends in childhood obesity are flattening out. This has been confirmed by an analysis carried out by the National Heart Forum (2009) which compared previous forecasts of obesity prevalence (using HSE data up to 2004), with new updated forecasts based on data between 2000 and 2007 (McPherson et al. 2009). The results show that the predicted prevalence of overweight and obesity in 2020 is considerably lower than previous forecasts (see table 3.6). There are encouraging signs that the rising trend may be levelling out. However, similarly to Rokholm, Baker and Sorenson (2010) and Olds et al. (2011), the report warns against complacency as the prevalence of overweight and obesity in children is still high and this has significant implications for the health and well-being of children.

Table 3.6 Revised forecasts for overweight and obesity in children

Source: McPherson et al. 2009

Finally, Stamatakis et al. (2010) reported different obesity prevalence projections for 2015 by using the prevalence rates in England between 1995 and 2007 published in the HSE (The NHS Information Centre 2009). Their results suggest there has been a marked increase in the prevalence of obesity between 1995 and 2004/05, followed by a tendency to level off or decrease to 2007, suggesting the obesity epidemic may be slowing down. They comment that the Foresight (Butland et al. 2007) predictions are likely to be over-estimated as they do not take into account the 2005-2007 prevalence which shows a consistent tendency for stabilisation of the trend. Assuming a linear trend, Stamatakis et al. (2010) predict the 2015 projected obesity prevalence in the 2-10 year old age groups is 10.1% in boys and 8.9% in girls; and 8.0% in males and 9.7% in females aged 11-18 years. These results are somewhat lower than those predicted by Foresight and are similar to those published in the National Heart Forum report (McPherson et al. 2009). Crucially, whatever methodology is used for determining obesity prevalence in children, the data clearly demonstrates that the prevalence of overweight and obesity in children in the UK has never been higher.

3.6 Summary

The use of BMI in children is recommended in clinical guidelines for the NHS in England. It is recognised as the best simple anthropometric measure currently

available and is low-cost, easy to use and acceptable to subjects. In particular for studies such as this, BMI can be collected by staff from a non-clinical background and provides a quick, non-invasive method to collect, monitor and provide feedback on weight status. However, BMI does have its limitations including its ability to measure excess body fat in children, and the lack of consensus concerning the cut-off points used to define overweight and obesity. For studies such as the current research change in BMI or BMI z-score is often used as the primary outcome with BMI percentile used for the referral criteria.

There is overwhelming evidence that the prevalence of childhood obesity has increased dramatically across the world over a relatively short time period. Recently there is evidence to suggest a levelling off of the epidemic in some geographical areas. Data for the UK has been collected though the HSE and NCMP. The NCMP is a census of eligible children which now provides unparalleled information regarding the weight status of school children in England. This data can also be explored to ascertain the levels of obesity at regional and local levels. Recent UK results suggest the obesity epidemic may be slowing down. However, Rokholm, Baker and Sorenson (2010) point out that this could only be a temporary phase that might be followed by further increases in obesity levels in the future. It remains clear that the number of obese children has never been higher than it is today and research into prevention and treatment remains a priority.

Chapter 4 – Review of the literature

4.1 Introduction

This chapter gives an overview of the literature concerning the treatment of childhood obesity and is divided into three sections. The first section discusses the systematic reviews concerning the treatment of childhood obesity that have been published from 2000 to 2012. The second section documents the original literature review undertaken during step 1 of the intervention mapping protocol (see chapter 5). This section reviews studies published between 1985 and 2006 that influenced the development of this programme, and highlights the factors that were considered in the design of the treatment programme. The final section is a review of family-based childhood obesity treatment programme RCTs undertaken from 2007 to 2012. This section describes the settings used for these programmes, the design of the studies, the key components included in the interventions and gives an insight into their effectiveness.

4.2 Systematic reviews

The Cochrane systematic review published in 2003 searched papers up to July 2001 and reported a lack of research on the treatment of childhood obesity, only finding 18 RCTs, many of which had small sample sizes or other methodological limitations (Summerbell et al. 2003). The authors, therefore, were unable to draw definitive conclusions from this review. A further systematic review examined the nature and effectiveness of family involvement (McLean 2003). Although few studies existed, they indicated that parental involvement is associated with weight loss in children (5 to 13 years of age) but not in adolescents (12 to 17 years of age), and that a greater range of behaviour change techniques (BCT) improves outcome. Both reviews drew attention to multi-component family-based interventions as a promising approach.

Wilfley et al. (2007) conducted a meta-analysis of RCTs involving lifestyle interventions for the treatment of childhood overweight. For inclusion, the studies had to be compared with a no treatment or information / education only group, rather than other active treatment groups. Fourteen RCTs published between 1975 and 2004 were included in the analysis. The authors found multi-component family-based

interventions were associated with modest but clinically important short-term improvements in child body size compared to standard care or no treatment control conditions.

An updated Cochrane review including trials of interventions to treat obesity in children or adolescents published up until May 2008 has been published (Oude Luttikhuis et al. 2009). A new comprehensive search strategy found 46 additional RCTs which met the inclusion criteria, making a total of 64 RCTs in the systematic review. Of the 64 trials, 54 RCTs focussed on lifestyle factors such as diet, physical activity and sedentary behaviours. For inclusion, the studies had to include a baseline and post intervention measurement of height and weight, with the primary outcome measure being change in BMI z-score or percentage overweight. Only two of the RCTs were from the UK (Hughes et al. 2008, Daley et al. 2006). The results of four behavioural interventions in children under 12 years which fulfilled the criteria to be pooled were analysed. The mean difference between the groups in BMI z-score favoured the behavioural intervention over standard care at the 6 month post-baseline follow-up (-0.06, 95% CI: -0.12 to -0.01), but there was no additional beneficial effect of the behavioural intervention over standard care at 12 months post-baseline (-0.04, 95% CI: -0.12 to 0.04). The analysis of behavioural interventions targeting children aged 12 years and older included results from only three of 12 interventions. The pooled effect for BMI z-score was in favour of the intervention compared with standard care or self-help at 6 months post-baseline (-0.14, 95% CI: -0.17 to -0.12), and persisted until the 12-month post-baseline follow-up (Oude Luttikhuis et al. 2009). Importantly, no adverse effects on psychological well-being, linear growth or eating disorders were found with behavioural interventions.

The overall conclusion of the 2009 Cochrane review was that it was difficult to recommend one intervention over another. However, several studies included in this review indicate that family-based lifestyle interventions which combine dietary, physical activity and behavioural components can produce ‘a significant and clinically meaningful reduction in overweight in children and adolescents’ (p.2) compared with standard care, self-help or control (Oude Luttikhuis et al. 2009). Combined interventions were more effective than interventions targeting diet or physical activity

alone. Furthermore, parental involvement was identified as being particularly useful in children under 12 years, but not in adolescents.

More recently Whitlock et al. (2010) conducted a systematic review of behavioural and pharmacological interventions and evaluated their effect on weight, weight-related co-morbidities and potential harm. The group evaluated thirteen behavioural interventions by assessing the intervention intensity measured by the number of contact hours; very low (<10 hours), low (10–25 hours), moderate (26–75 hours) and high (>75 hours). The review found the comprehensive behavioural interventions which were of moderate to high intensity were the most effective in the short-term, and limited evidence suggested these improvements in weight status could be maintained over the 12 months after the end of the intervention. The team reported no evidence of harm associated with these programmes. These findings support a tiered approach to treatment for childhood obesity as shown in figure 2.2 with the intensity of approaches associated with the degree of obesity and the amount of specialist support required.

In the two latest systematic reviews Sung-Chan et al. (2012) examined fifteen family-based childhood obesity RCTs with reference to two theoretical frameworks; behaviour theory and family system theory, and Ho et al. (2012) evaluated the effect of thirty-eight lifestyle interventions on childhood obesity. Sung-Chan et al. (2012) identified two types of interventions based on the behaviour theory; behavioural approaches to family-based healthy lifestyle interventions and behavioural approaches to family-based healthy lifestyle interventions plus parent education. There were also two types of intervention identified for the family system theory; family therapy and family therapy plus behaviourally oriented psycho-education. The review supported the use of a family-based model as it produced positive effects in overweight children's weight status. When the two types of theoretical frameworks were analysed, interventions based on the behaviour theory were more effective than the family system theory therapy approach. However, it should be noted there were only two family therapy RCTs identified so the results should be treated with some caution. Comparison of the behavioural approaches showed the family-based lifestyle intervention involving primarily one parent proved more effective than the family-based intervention with parent education. Although the family-based healthy lifestyle interventions achieved better outcomes, the authors recognised the other three approaches should not be

underestimated for their potential when researchers are planning future interventions. These three newer approaches require further exploration and rigorous evaluation as there were fewer of these studies for examination in this review.

Ho et al. (2012) examined the effect of lifestyle interventions incorporating dietary components on weight change in overweight and obese children. They found the lifestyle interventions produced a significant weight loss compared with no treatment control conditions; BMI (-1.25kg/m^2, 95% CI: -2.18 to -0.32) and BMI z-score (-0.10kg/m^2, 95% CI: -0.18 to -0.02). The authors also reviewed the results of studies comparing lifestyle interventions to usual care. Results showed a significant immediate effect on BMI (-1.30kg/m^2, 95% CI: -1.58 to -1.03), and post-treatment effects were seen on BMI up to one year from baseline (-0.92kg/m^2, 95% CI: -1.31 to -0.54).

In their conclusions, Sung-Chan et al. (2012) highlighted the need for methodological rigour in childhood obesity weight management interventions. They suggest better outcomes would be achieved if more attention was given to the methodological design of studies. Both Sung-Chan et al. (2012) and Ho et al. (2012) drew particular attention to the need to determine optimal treatment intensity and duration, the need for follow-up measurements to assess long-term effectiveness, and standardisation of outcome measurements to enable comparisons to be made across studies.

4.2.1 Summary of systematic reviews

There are common themes identified by the systematic reviews of childhood obesity treatment interventions. Parental involvement appears to be beneficial in improving outcomes for children under the age of thirteen years. For children, parents normally have the resources and responsibility to create and maintain a healthy family environment so their involvement is key. Previous research has also demonstrated multi-component family-based lifestyle interventions which combine diet, physical activity and behavioural components are the treatment of choice, with studies demonstrating that a greater range of behaviour change techniques improves outcome. One review examined programme duration and intensity and found the most effective programmes used a moderate (26 – 75 hours) to high (>75 hours) intensity intervention design. There was limited evidence to suggest children attending programmes

managed to maintain their positive change in weight status over the 12 month period following the intervention. However, it was recommended in a number of reviews that more studies need to follow-up families as part of their protocol to be able to ascertain whether beneficial long-term changes are maintained or improved. Finally, there was no evidence of adverse effects to psychological well-being, linear growth or eating disorders caused by being involved in a childhood obesity treatment programme.

4.3 Key studies reviewed in the development of the programme

At the time of developing this intervention the evidence base for multi-component family-based programmes to treat childhood obesity with parents as the main agents of change mainly came from the USA (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000, Israel, Stolmaker and Andrian 1985) and Israel (Golan and Crow 2004, Golan, Kaufman and Shahar 2006, Nemet et al. 2005). These studies are described below and indicate the components of successful childhood obesity treatment programmes identified by these research teams. The evidence table for these studies can be found in appendix 1.

4.3.1 Studies from the USA

Fifteen of the studies in the NICE guidance (NICE 2006), and twelve of the studies in the Cochrane review (Oude Luttikhuis et al. 2009), were from Epstein's group in the USA, thus contributing considerably to the evidence base. This group have evaluated 'Family-Based Behavioural Treatment' (FBBT), examining different lifestyle factors, behaviour management approaches and/or target groups, delivered to groups over 8-12 weeks (Epstein et al. 1994). Their programmes used the 'Traffic Light Diet' which is designed to decrease energy consumption and promote a balanced diet. Foods from the five food groups are colour coded according to their caloric density per average serving: green for 'go', yellow for 'approach with caution' and red for 'stop'.

The group conducted a ten year follow-up of the programme in 76 families comprising obese children aged 6 to 12 years of age and their obese parents who had been randomised to one of three groups; child and parent targeted for reinforcement for weight loss and behaviour change, child only group reinforced for child behaviour

change and weight loss, and a non-specific control group who received the standard programme. Long-term changes in weight, measured by decrease in percentage overweight, were better when the child and parent were targeted together (-11.2% at 5 years, -7.5% at 10 years), compared with targeting the child alone (+2.7% at 5 years, +4.5% at 10 years) and the non-specific control group (+7.9% at 5 years, +14.3% at 10 years) (Epstein et al. 1990). This study included 'intact' families and both parents were expected to participate in the intervention. Data regarding attendance was not given. At 10 year follow up there were no significant differences in change in parent percent overweight for any of the groups.

This study was the first to provide evidence of the positive long-term effects of behavioural family-based treatment programmes for childhood obesity. The results demonstrate targeting child and parent together, compared with child alone and non-specific reinforcement, proved more successful in improving the weight status of the children included in this study who were between 6 and 12 years of age. This also enables both children and parents to be supported when both are overweight or obese. Importantly, the study demonstrated there were no long-term effects on final height attained for the children in the study contrary to previous studies which reported short-term effects of weight loss on child growth (Dietz and Hartung 1985, Lloyd, Wolff and Whelen 1961).

In a different study by the same group (Epstein et al. 2000) the researchers compared the effect of an intervention aimed at decreasing sedentary behaviours and increasing physical activity at two levels of intensity in obese children aged 8 to 12 years of age. Ninety families were recruited to the study, with children and one parent actively taking part in the intervention. The participants were randomised into one of four groups; low dose decreased sedentary behaviour (n=23), high dose decreased sedentary behaviour (n=22), low dose increased activity (n=22) and high dose increased activity (n=23). The intervention took place over 6 months with 16 weekly meetings followed by 2 biweekly and 2 monthly meetings. Meetings comprised of families meeting with individual therapists to have their weight monitored and to discuss progress, followed by separate child and parent group sessions. All study groups followed the 'Traffic Light Diet', self-monitoring, BCTs such as goal setting and positive rewards, and

maintenance of behaviours. The primary outcome measurement was change in percentage overweight at six and 24 months.

Seventy-six families completed the study and there was no statistically significant difference between any of the groups at six or 24 months. Twenty-eight percent of the parents who completed the study were male. There was a significant decrease in mean percentage overweight from baseline to six months (25.5%), and to 24 months (12.9%) across all groups. Obese participating parents showed a significant (p<0.001) decrease in weight from baseline to six months (-12.9kg), and to 24 months (-7.1kg) across all groups.

The lack of control group in this study is a limitation. However, the results between the groups are similar demonstrating that reducing sedentary behaviours is an alternative to increasing activity in a comprehensive family-based childhood obesity treatment programme. This study was based on targeting certain sedentary behaviours which were recorded through self-report. Whilst the self-report data demonstrates a reduction in the targeted sedentary behaviours, it is not possible to understand if the time made available by reducing these behaviours was spent on increasing physical activity or switched to other sedentary behaviours. The authors point out that if appealing and enjoyable physical activity is not available then children may not increase their activity when sedentary behaviours are targeted for reduction, but just change to other sedentary behaviours. Despite this the results show positive changes for both decreasing sedentary behaviours and increasing physical activity. This knowledge increases the behaviour change options for families engaged in weight management programmes, and provides further evidence to support both of these behaviours being incorporated in to a multi-component weight management programme for children.

Also in the USA, Israel, Stolmaker and Andrian (1985) conducted an RCT with 33 overweight children aged 8 to 12 years of age and their parents. Families were assigned to one of three intervention groups: a multi-component behavioural weight reduction programme, with and without an added parent-training course in child management skills, and a waiting list control group.

At the end of the 9 week programme both treatment groups significantly reduced their body weight (measured in pounds) ($F(2,29) = 14.43$, $p<0.001$) and percent overweight ($F(2,29) = 15.15$, $p<0.001$). For reduction in body weight the combined treatment conditions differed from the control group ($F(1,29) = 31.92$, $p<0.001$), but the two treatment groups did not differ from each other. At one-year follow-up, the parent training group maintained the improvement in percentage overweight compared with the group that just received the weight reduction programme. Data was not provided on the gender of the parents attending the intervention. At the end of the 9 week programme a comparison of the change in weight of the two treatment groups showed a difference ($F(1,20) = 12.69$, $p<0.01$) favouring the parent training group. There were no significant correlations between parent and child changes in weight and percent overweight. At one year follow-up there were no differences between the treatment conditions or between the end of programme results and the one year follow-up results. There was a significant correlation between overweight parents' and children's changes in percent overweight over the one year period ($r(10) = 0.82$, $p<0.002$).

This study was based on a small group so is probably underpowered, but significant differences were seen in positive changes in weight status in both treatment groups. The authors do not provide information regarding whether the groups' parenting skills differed at baseline. However, the results suggest including parenting skills in an intervention could be important in sustaining positive lifestyle changes.

4.3.2 Studies from Israel

A second group of researchers making a significant contribution to the evidence for the treatment of childhood obesity are based at the Hebrew University of Jerusalem, Israel. These researchers have focused on the treatment of childhood obesity using multi-component family-based programmes with parents as the main agents of change.

Golan and Crow (2004) reported a seven year follow-up of a RCT of 60 obese children (6 to 11 years of age) in which parents or children were targeted as the exclusive agents of change. Parents attended 14 one hour group sessions including eating and activity behaviour modification, decreasing stimulus exposure and parental modelling. Parents were also encouraged to practice 'authoritative' parenting where the parents

are both firm and supportive using a child-centred approach and encourage children to be independent but still placing controls and limits on their actions (Rhee et al. 2006). The children who attended group sessions were prescribed a diet, and discussions included physical activity, eating behaviour modification and self-monitoring.

At the end of the intervention the children in the parent-only group achieved a significantly higher reduction in percent overweight compared with the children in the child-only group (14.6% vs. 8.43%, $p<0.03$). At one and two year follow-up the reduction in percent overweight for the children in the parent-only group was statistically significant compared with that of the child-only group (-13.6% vs. 0.0%, $p<0.05$) and (-15% vs. -2.9%, $p<0.01$), respectively. At the seven year follow-up both treatment groups demonstrated significant weight loss (parent only = 29% vs. child only = 20.2%, $p<0.05$). The differences between groups in overweight reduction at each time-point were significant ($p<0.000$). The paper did not document the percentage of mothers, fathers or both parents who took part in the parent-only groups. Parents' weight status and change in parental weight status was also not reported.

Golan and Crow (2004) used change in children's overweight status to assess effectiveness of the programme with results showing the parent only group having a greater weight loss at the end of the intervention and at one year, two year and seven year follow-up appointments compared with the child only group. An assessment of parenting style at the start and end of the intervention would have provided data to suggest the mechanism by which these positive changes were occurring, and provide information regarding the use of this type of intervention to improve parenting practices. Regarding study design, there was a small sample size and the control group was provided by the child-only group as this represented the norm in Israel. It would have been useful to have a family group (i.e. child and parent) to compare the results with to reflect the treatment approach in many other countries.

A further study conducted by Golan, Kaufman and Shahar (2006) randomised 32 families with obese children aged 6 to 11 years of age to either a group where the parents were targeted alone or a group where parents and children attended together. Both groups received a 6 month educational and behavioural programme for a healthy lifestyle including advice on healthy eating, encouragement to increase daily physical

activity and decrease in sedentary behaviours. Parents were coached in 'authoritative' parenting and encouraged to foster an authoritative feeding style where they determine what foods are offered and the children determine the amount eaten. Where families were 'intact' (n=27), both the mother and father participated in the programme. For single parent families (n=5), only the mother attended.

The parent only group showed a significant reduction in overweight status and BMI z-score compared with the parent–child group ($F(1,28) = 11.3$, $p=0.02$; $F(1,28) = 5.7$, $p=0.024$, respectively). Results at 1 year follow-up showed an average reduction of 12% in percentage overweight ($p=0.045$) and 0.5 BMI z-score ($p=0.025$) in the parents only group, with a 0.4% increase in average percentage overweight and 0.1 BMI z-score in the parent-child group, both not significant. The percentage overweight of parents did not change significantly at the end of the programme in either group.

Again, these results suggest that for children aged 6 to 11 years of age interventions delivered to parents alone may be more effective than those delivered to parents and children together. In the parent only group the attendance data showed higher full attendance (both parents), than in the parent-child group. This could suggest that when both parents attend the intervention the results are better due to both parents taking responsibility and working together to achieve the relevant changes.

Also based in Israel, Nemet et al. (2005) randomised fifty-four obese children aged 6 to 16 years of age to either a 3 month combined dietary and exercise programme, or a control group who received normal care of one nutritional consultation and were instructed to perform physical activity three times per week. All participants were encouraged to reduce sedentary activity. Participants were invited to attend for a 1 year follow-up appointment.

At the end of the three months there were significant differences in change in body weight (-2.8 ± 2.3kg vs 1.2 ± 2.2kg, $p<0.05$) and BMI (-1.7 ± 1.1kg/m^2 vs -0.2 ± 1.0 kg/m^2, $p<0.05$) in the intervention group compared with the control group. At 1 year follow-up there were also significant differences in body weight (0.6 ± 6.0kg vs 5.3 ± 2.7kg, $p<0.05$) and BMI (-1.7 ± 2.3kg/m^2 vs 0.6 ± 0.9kg/m^2, $p<0.05$) between the intervention and control groups.

Although only a small sample, the results suggest a 3 month multi-component intervention can have beneficial effects on weight status in both the short-term and at one year follow-up compared to normal care. The authors report that the results seen in this study at the one year follow-up are similar to the results reported for a different group of obese children who participated in a similar structured programme for 12 consecutive months (Eliakim et al. 2004). This suggests a brief programme, over a 3 month period, can be effective and the success achieved during the length of the intervention can be sustained in the longer-term. This is an important consideration for the design of the intervention in this thesis. A limitation of this study is that data regarding the parents who participated in the study is not given. Therefore, no information regarding whether fathers as well as mothers were involved is known, and change in parental weight status is not given.

4.3.3 Implications for the current study

The research described in the USA and Israel included studies targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and included BCTs. The evidence showed this type of multidisciplinary programme has achieved success in improving weight status in children aged 6 to 12 years of age (and up to 16 years of age in one study), with parent only groups and parent-child combined groups. Work by Epstein (Epstein et al. 1990, Epstein et al. 1994, Epstein et al. 2000) promoted 'family-based' treatment with both children and their parents/carers included in the sessions, In a further paper (Epstein et al. 1998) the authors assert emphatically the importance of the intervention and the lifestyle changes being 'family based' with the support of the parents and family fundamental to any success. In comparison, Golan and Crow (2004) and Golan, Kaufman and Shahar (2006) demonstrated that parent-only interventions may be more effective, and addressing parenting in addition to lifestyles resulted in improved results than treating parents and children together.

To resolve the conflicting evidence concerning the involvement of parents exclusively or within the family results from the systematic reviews and recommendations in the NICE guidelines (NICE 2006) were also considered. McLean (2003) reported that

parental involvement was associated with weight loss in children and Oude Luttikhuis et al. (2009) concurred with this and recommended parental involvement for children 12 years and under. The NICE guidance states 'individual as well as family-based interventions should be considered, depending on the age and maturity of the child' (p. 21) (NICE 2006). Why parental involvement improves child weight status outcomes in programmes is unclear in the present literature. Possible mechanisms include; modelling behaviour, providing healthier or less food, increasing the opportunities to exercise and improving parenting skills.

As this intervention was being developed for children aged 8 to 13 years of age a pragmatic decision needed to be made regarding the model of delivery. Results from the needs assessment for this project (section 5.4.1), which was being carried out at the same time as this literature review, revealed that a family-based programme was required in the local area which combined healthy eating advice, parenting skills and physical activity sessions. The author gathered further information from both the Epstein and Golan research groups regarding the delivery methods and content of their programmes (personal communications). The combination of the requirements from the needs assessment, and information from the USA and Israel research groups led to the development of a structured family-based programme. The weekly programme offered a family-based workshop for parents and children together, followed by a parent only session, during which time the children attended a physical activity class. It was planned this way to try and capitalise on the positive benefits demonstrated by previous studies whilst addressing the requirements of the local population identified by the needs assessment.

4.4 Review of family-based RCTs conducted from 2007 to 2012

Since the development and initial implementation of the programme there have been a large number of papers published concerning interventions to treat childhood obesity. Thirteen RCTs, conducted between 2007 and 2012, describing family-based multi-component lifestyle treatment programmes targeted at overweight and/or obese children aged 4 to 16 years of age are discussed in this section. Studies targeting children aged 13 years and over exclusively, those focussing on the treatment of severe pediatric obesity only and those including children with mental health

conditions, were excluded from this review. Six of the interventions were conducted in Western Europe, five in Australia and two in the USA. The evidence table for these studies can be found in appendix 2.

4.4.1 Treatment interventions delivered in Western Europe

4.4.1.1 SCOTT (Scottish Childhood Overweight Treatment Trial)

The SCOTT RCT included 134 five to eleven year old obese children (BMI >98th centile when plotted on the UK 1990 charts), who were referred to hospitals in Glasgow and Edinburgh. The trial compared an intensive behavioural approach comprising around 5 hours of one-to-one treatment by a paediatric dietician with standard dietetic care (control) involving three to four outpatient appointments delivered by paediatric dieticians during six to twelve months with around 1.5 hours of contact (Hughes et al. 2008). The standard dietetic care was measured by using a process evaluation carried out by the dieticians who conducted the standard care and confirmed the description of the control group treatment. The intervention, delivered over a 6 month period, used counselling and behavioural strategies to encourage participants to change their diet to reduce intake of foods high in fat and sugar, and increase intake of fruit and vegetables, increase activity and reduce sedentary behaviour. Data was not provided regarding the number or gender of the parents who attended the intervention.

The results showed no significant differences between the intervention relative to standard care in the change in BMI z-score from baseline to 6 months (median difference between groups: 0.03, 95% CI: -0.05 to 0.11, p=0.4) or from baseline to 12 months (-0.04, 95% CI: -0.17 to 0.07, p=0.5). Both groups showed a small statistically significant reduction in BMI z-score at the 12 month post-intervention follow-up, between -0.22 to -0.04 (95% CI) for the intervention group and between -0.26 to -0.08 (95% CI) for the standard care group. Weight increased significantly for both groups from baseline to 6 months and baseline to 12 months (intervention: 95% CI: 5.4 to 7.8 kg, control: 95% CI: 5.5 to 7.7 kg). There were significant increases in physical activity (median difference between groups: -112, 95% CI: -199 to -31, p=0.009), and significant decreases in sedentary behaviour (median difference between groups: 3.60, 95% CI: 0.80 to 6.30, p=0.009) in the intense intervention group, relative to standard

care. No data was provided concerning parental weight status at the beginning or end of the intervention.

In light of the modest benefits, the authors proposed that a more intense (greater number of appointments over the study duration) and / or sustained (longer study design) intervention may be required. It should also be noted that being on a waiting list and being 'identified' may motivate people to make changes. The children included in the study were also very overweight (BMI z-score > 3) and may have been resistant to treatment. The control group in this study was 'standard dietetic care' which is not universally available in England for the treatment of childhood obesity. Thus, the benefits are difficult to assess without a comparison group of families not offered any treatment, reflecting the situation in many parts of England.

4.4.1.2 Family-based behavioural treatment

Croker et al. (2011) reported results of their study using 'Family-Based Behavioural Treatment' (FBBT). This intervention was based on Epstein's FBBT programme and was adapted for use in a UK clinical setting. The programme was targeted at families with overweight or obese children aged 8 to 12 years and comprised fifteen sessions over a 6 month period. The programme emphasised whole-family lifestyle changes and used the 'Traffic Light Diet' as a guide for healthy eating, and set key physical activity targets in line with the current UK recommendations. Families were randomised to the intervention group or a 6 month waiting-list control group. Data was not provided regarding whether mothers or fathers, or both, attended the intervention, only that one parent or carer was required to attend the sessions.

There were no significant between-group differences for the primary outcome measures of BMI z-score and BMI from baseline to 6 months. Both groups showed a significant reduction in BMI z-score at the end of the 6 month period (intervention: -0.11 (SD 0.16), $p<0.01$, control: -0.10 (SD 0.16), $p<0.01$), but there was no change in BMI in either group (intervention: -0.36 (SD 1.06), control: -0.03 (SD 1.07)). Parent-reported children's quality of life improved in the treatment group (3.81, SD 9.08, $p<0.05$), there were improvements on the Children's Eating Attitudes Test (CHEAT) (Maloney,

McGuire and Daniels 1988) (-2.30, SD 6.41, $p<0.05$) and overall children's well-being improved, measured using the Self-perception Profile for Children (SPPC) (Harter 1982) (0.20, SD 0.64, $p=0.05$). Parental weight status at baseline was reported but change in parental weight status at the end of the intervention was not.

The researchers commented that although their results are not as good as the impressive average BMI z-score changes at 6 months (-1.20) seen in Epstein's work (Epstein et al. 2007), they used an intention-to-treat analysis which should give a truer picture and should not inflate any effect due to drop out. Their results are also comparable to some other UK studies. Regarding the control group, the researchers comment that 'families received considerable input prior to randomisation, which may have been sufficient to engender some change' (p. 24). It appears this may be true for this FBBT study and their control group were ready and willing to make changes which may not be representative of 'typical' obese children in the community. The changes made to the intervention when delivering to UK groups such as changing calorie goals to goals on food types and portion sizes, removing the need to weigh children daily and not incentivising participation may have diluted the intended intervention and reduced its impact. The difficulties in taking an 'off the shelf' programme and trying to implement it in a local community are apparent here and it raises questions about the generalisability of programmes such as FBBT.

4.4.1.3 MEND

The MEND (Mind, Exercise, Nutrition, Do it!) programme is a multi-component family-based healthy living programme of nutrition education, exercise and behaviour modification delivered by non-specialists in community settings. The programme consists of 18 sessions delivered over a 9 week period with each session lasting 2 hours. Sessions are normally delivered in community venues such as leisure centres, community centres or schools. The MEND programme was first piloted in 2002 and started to work with a small number of PCTs in 2005. The programme now runs extensively throughout the UK.

Sacher et al. (2010) conducted an RCT of the MEND programme including one hundred and sixteen families with obese children aged 8 to 12 years of age who were

randomised to either the intervention group or a 6 month waiting-list control group. The RCT was carried out over five sites in the UK. The RCT protocol followed the standard 9 week programme and free family access to a swimming facility was available for a further 12 weeks. Data was not provided regarding whether mothers or fathers, or both, attended the intervention, only that one parent or carer was required to attend the sessions.

The results showed a significant difference in BMI z-score at 6 months post-baseline between the groups (-0.24, 95% CI: -0.34 to -0.13, p<0.0001, n=82), with the intervention group reducing their BMI z-score by -0.30 at 6 months post-baseline (95% CI: -0.36 to -0.23, p<0.0001, n=71), and -0.23 at 12 months post-baseline (95% CI: -0.33 to -0.13, p<0.0001, n=42). Significant between-groups differences were also reported in physical activity levels, sedentary behaviours, cardiovascular fitness and self-esteem. Unusually, all the children who started the 9 week programme completed it, with 62% attending for a 6 month follow-up review. Intention-to-treat analysis was not reported. There was no change in parental weight status between baseline and six month follow up for either group, and parents in the intervention group increased their BMI (0.2kg/m^2, 95% CI: -0.2 to 0.7) at twelve month follow-up.

The results of the RCT indicate MEND may be an effective intervention that can be implemented in community settings in the UK. The published results demonstrate it was acceptable to families and the researchers suggest the standardization of the programme means it can be delivered by community practitioners who have no previous experience of delivering weight management programmes. A limitation of the study was that the researchers conducting the outcome assessments were not blinded due to the waiting list control design. This is a potential source of bias. However, the research team did try to address this by using subjective measures. For example, waist circumference was measured twice by two different researchers. The authors acknowledge that selective drop out may have influenced the results and the short follow-up period means it is difficult to make any conclusions about the long-term effects of the programme.

4.4.1.4 WATCH IT

The WATCH IT programme is a community-based childhood obesity treatment service run in disadvantaged areas of Leeds, UK. To develop the programme the views of relevant professionals were gathered and young people at school and the community were consulted. The key areas identified were a flexible approach, local access (but not in a school or health setting) and frequent contact. The programme began to be developed in 2003 and delivery started in 2004 and continues to be delivered (Rudolf et al. 2006).

Bryant et al. (2011) reported the results of a feasibility RCT delivered by non-registered healthcare professionals who were described as health trainers. They had brief training in nutrition, physical activity, mental health and child protection, and then received regular supervision from a dietician, psychologist, sports physiologist and paediatrician. Families were asked to commit to attend for 4 months, with the option of continuing for a further 4 or 8 months. The programme involved one-to-one weekly appointments for the child and parent, weekly group activity sessions and parenting group sessions once the one-to-one sessions had ended. The intervention was delivered away from clinical settings in local sports and community centres.

In the RCT seventy obese participants aged 8 to 16 years of age were randomised to either the intervention group or a 12 month waiting-list control group. Eighty-nine percent of the parents in the intervention group and ninety-seven percent of the parents in the control group were mothers. The mean change in BMI z-score at 12 months post-baseline was 0.03 (95% CI: -0.05 to 0.11) in the intervention group, and -0.03 (95% CI: -0.12 to -0.06) in the control group. Between group differences were not presented in the study. Parental height and weight were measured as part of the intervention but the results were not published.

This study was not powered to demonstrate effectiveness of the intervention with only 35 children in the intervention group. The authors comment that it did, however, allow them to develop a robust protocol for a definitive multi-centre trial, which has not taken place yet. In this study the majority of the families were White British. This suggests the recruitment strategy used by the research team may not have been suitable for

families from all ethnic backgrounds, and it means the intervention was not tested with children and families from BME groups.

4.4.1.5 The Family Project

The Family Project was a multi-disciplinary family-based programme delivered on the island of Jersey (Coppins et al. 2011). The programme was delivered in a school by health professionals, a clinical psychologist and physical activity instructors. Workshops focused on healthy eating, physical activity, reducing sedentary behaviour, behaviour change and psychological well being. The intervention lasted for one year and during this time families attended 8 hours of workshops delivered at the weekends and weekly physical activity sessions during term time. Participants were also followed up to 24 months and offered simple body composition monitoring during this time. To evaluate the intervention a RCT design was used. Sixty-five participants aged 6 to 14 years of age who were overweight or obese were recruited and randomly allocated to either the intervention or control group.

The results showed a significant difference in BMI z-score at 12 months post-baseline between the groups (-0.09, 95% CI: -0.26 to 0.09, p=0.32), with the intervention group reducing their BMI z-score by -0.17 at 12 months post-baseline (95% CI: -0.26 to -0.08) and -0.44 at 24 months post-baseline (95% CI: -0.7 to -0.18). The team also presented the results for the control group after they had gone through the intervention. This group achieved a reduction in their BMI z-score of -0.08 at 12 months post-baseline (95% CI: -0.24 to 0.07), and -0.14 at 24 months post-baseline (95% CI: -0.35 to 0.06). Twenty percent of participants dropped out of the intervention group and ten percent of the control group dropped out. Intention-to-treat analysis was not reported.

The authors propose the enhanced results in the second year for those who were enrolled in the first intervention group suggests that for greatest effect participants need to start in the intervention as soon as possible after recruitment. Therefore, the waiting-list control design of this research may not have been appropriate. This has implications for the design of future studies and creates concerns regarding the use of traditional RCTs for evaluating the effectiveness of childhood obesity treatment programmes. The authors also commented that children did not participate in the twice

weekly leisure-centre based sessions as much as they had expected. Although only a small study these results give evidence that after an intervention participants are able to maintain and improve their weight management efforts when offered body composition monitoring at 6 monthly intervals.

4.4.1.6 Family-based group treatment in Finland

Kalavainen, Korppi and Nuutinen (2007) conducted a RCT to compare the efficacy of a 6 month family-based group treatment programme and routine treatment control group. The family-based treatment consisted of fifteen separate sessions for parents and children delivered in the outpatient clinic of a hospital. The first ten sessions were delivered weekly and the next five sessions fortnightly. The programme focussed on promoting a healthy lifestyle (healthy diet, increasing physical activity, decreasing sedentary behaviour), and supporting the well-being of the children, rather than weight management. The children's sessions included non-competitive physical activities to increase their confidence and motivation to take part in activity outside of the sessions. The routine treatment was two appointments for children with a school nurse in a health centre. Appointments were 30 minutes in duration and included information on weight management, eating habits and physical activities. Children aged 7 to 9 years of age with weight for height 120 to 200% were eligible for inclusion in the study.

Seventy children were randomised to either the group treatment programme or routine programme. After the 6 month intervention the children in the group treatment improved their BMI z-score (-0.3, 95% CI: -0.4 to -0.3) more than those in the routine group (-0.2, 95% CI: -0.3 to -0.1). The difference between the two groups was significant (p=0.005). Follow-up data was collected 6 months after the end of the intervention. The results show the BMI z-scores decreased in both the treatment group (-0.2, 95% CI: -0.3 to -0.1) and the routine group (-0.1, 95% CI: -0.2 to 0.0). The difference between the two treatment groups remained significant.

Kalavainen, Korppi and Nuutinen (2011) published the results of follow-up reviews undertaken two and three years after the intervention had begun. Sixty-nine of the original children participated in the two year follow-up and sixty-eight in the three year follow-up. There were no significant differences in changes in BMI z-score from

baseline to 2 or 3 years in both groups, although BMI z-score did decrease from baseline to 2 and 3 years in both groups: routine group; two year follow-up (-0.2, 95% CI: -0.3 to -0.1), three year follow-up (-0.3, 95% CI: -0.5 to -0.1), group programme; two year follow-up (-0.2, 95% CI: -0.4 to -0.1), three year follow-up (-0.3, 95% CI: -0.5 to -0.2).

The results show the short-term positive changes in BMI z-score achieved at one year post-intervention were not sustained at 2 and 3 years after the intervention. Maintaining the positive changes is essential to achieve long-lasting beneficial changes in health status. This study was based on a small sample size and lacked a no intervention control group. By not including a true control group it is not possible to generalise the results to all obese children.

4.4.2 Treatment interventions delivered in Australia

4.4.2.1 LEAP

The treatment of childhood obesity has been the focus of a number of recent RCTs conducted in Australia. McCallum et al. (2007) reported the outcome data from the LEAP (Live, Eat and Play) trial. This study compared an intervention involving four GP sessions over 12 weeks using solution-focused therapy, with a control group who received no intervention. The GPs delivering the intervention set and recorded appropriate healthy lifestyle goals with families and had a personalised 20 page 'family folder' to assist them at the sessions. One hundred and sixty-three children aged 5 to 9 years of age who were classified as overweight or obese (using IOTF cut off points) but with a BMI z-score of < 3 took part in the study. The primary outcome measures were BMI and BMI z-score and results were reported for nine and fifteen months post-randomisation.

At nine months the mean BMI z-score had reduced for the intervention group from 2.0 (0.5) at baseline to 1.96 (0.57), and changed for the control group from 1.9 (0.5) to 1.93 (0.57). At 15 months the mean BMI z-score was 2.0 (0.68) for the intervention group and 1.92 (0.59) for the control group. There was no significant difference for the BMI

z-score between the two groups at either of the follow-up points; 9 months (-0.09, 95% CI: -0.2 to 0.02, *p*=0.12) and 15 months (-0.03, 95% CI: -0.17 to 0.1, *p*=0.62).

This study did not meet its primary aim of a sustained improvement in BMI for those in the intervention group compared to the control. The authors offer a number of ideas for this. Firstly, the 'dose' of the intervention may have been too low. Families only received four sessions over 12 weeks and perhaps more sessions are required during this time, or the 12 week period of support needs to be extended. Secondly, the solution-focussed approach may have led families to set goals that were not addressing BMI. Finally, there was a lack of quality control on the GP consultations and no objective monitoring of the consultations was conducted. The use of GPs to deliver interventions such as this is worthy of further research as they are an established and trusted health professional, and GP practices are normally easily accessible to families in local communities. However, it is worth noting the refusal rate of 49% which seems high compared with other childhood obesity interventions, and there was a relatively low compliance with only 41% attending all four GP appointments. This raises questions concerning the value families placed on receiving the intervention from their GP. In addition, using GPs to deliver a childhood obesity intervention would be costly, and prohibit the scaling of the model for more children.

4.4.2.2 Triple P – Positive Parenting Programme

Golley et al. (2007) conducted a RCT comparing two child weight management interventions; parenting-skills training alone (P) and parenting-skills training with intensive lifestyle education (P + DA), with a 12 month waiting list control (WLC) group. The parenting skills training utilised the Positive, Parenting Program (Triple P) which facilitates and supports parents to undertake family lifestyle change. The parenting skills training consisted of 4 weekly appointments followed by 3 monthly 15 to 20 minutes individual telephone sessions. Those on the parenting-skills training with intensive lifestyle education received the standard Triple P programme and received an additional seven intensive lifestyle support group sessions focusing on family-focused healthy eating. The WLC group had minimal contact over the 12 months. One hundred and eleven children aged between 6 and 9 years of age who were classified as overweight or obese (using IOTF cut off points) but with a BMI z-score of < 3.5 took

part in the study. The primary outcome measure was change in BMI z-score at 6 and 12 months after baseline.

For all three groups there was a significant decrease in mean BMI z-score from baseline to 12 months (P: -0.15 (SD 0.47), P + DA: -0.24 (SD 0.43), WLC: -0.13 (SD 0.57, p=0.76). There was no statistically significant difference in BMI z-score between groups at 12 months. Analysis of the results by gender showed boys in both intervention groups had significantly lower BMI z-scores at 6 and 12 months compared with baseline (P group; 6 months: p=0.004, 12 months: p=0.01 and P + DA group; 6 months: p=0.02, 12 months: p=0.01).

The gender difference in intervention effect is worthy of note. The reason for this difference is unclear and the authors suggest that it may be due to truncal adiposity in Australian children reportedly increasing more rapidly in girls than boys (Garnett et al. 2005). There may also be environmental factors or influences promoting overweight in children that make it harder for girls to reverse the trend in truncal adiposity. The authors comment that the effect size of the interventions in the study may have been diluted by the intention-to-treat analysis carried out. However, the intention to treat procedure was carried out for those families who did not attend all the sessions but the 6 and 12 month analysis reported was only for those who were assessed at each time point. Overall, the results suggest potential for this type of intervention, particularly in boys. However, future studies would need to have a larger sample size to allow fully powered gender subanalyses. In addition, a parent group who receive the intensive lifestyle education intervention alone would be required to explore the role of the two interventions and the potential synergy between them.

4.4.2.3 The PEACH RCT

The PEACH (Parenting Eating and Activity for Child Health) RCT was reported by Magarey et al. (2011). The study followed on from the study by Golley et al. (2007) described above. The PEACH intervention was targeted exclusively at parents of children aged 5 to 9 years of age who were classified as overweight or obese (using IOTF cut off points), but with a BMI z-score of < 4.0. The RCT compared the effectiveness of two interventions: the healthy lifestyle education with parenting skills

training (P + HL) and the healthy lifestyle education only intervention (HL). The interventions included 12 (P + HL) or 8 (HL) 90 to 120 minute group sessions and 4 telephone appointments delivered over 6 months. The P + HL group received the Triple P programme prior to the lifestyle component. The HL group received the lifestyle component only. The groups were open to both parents but mostly attended by mothers. Whilst parents attended the intervention, children and siblings were able to participate in fun activity sessions which provided optional child care. One hundred and sixty-nine children completed a baseline assessment and were randomly allocated to either the P + HL or HL group. The primary outcome measure was change in BMI z-score at 6, 12, 18 and 24 months after baseline.

For both groups there was a significant decrease in mean BMI z-score from baseline to 6 months (-0.26, 95% CI: 0.20 to 0.31, $p<0.001$). Results for the rest of the follow-up data showed this change was maintained over time ($p<0.001$). Overall, there were no differences between the groups and in contrast to the results presented by Golley et al. (2007), in this study there was no time-by-gender interaction. However, analysis of just the baseline and 6 month data for both groups revealed a weak group by time interaction ($p=0.034$) (P + HL: -0.36, 95% CI: 0.26 to 0.45, HL: -0.30, 95% CI: 0.20 to 0.39). This difference was lost over time.

A positive of this study is that the changes achieved at 6 months post baseline were maintained at the 24 month post baseline assessment with no additional intervention. This result suggests that for children 5 to 9 years of age targeting parents as the agents of change is an effective strategy for weight management in the short- and longer term. The authors suggest that the lack of difference between the groups may be due to the generic nature of the Triple P programme. The programme was designed to address children's behaviour and improve parenting skills rather than focus on obesity and healthy living. Modifying the programme to include specific strategies for weight management may enhance its effectiveness and result in better outcomes in child obesity interventions.

4.4.2.4 Group Lifestyle Triple P

Group Lifestyle Triple P is a modified version of the Triple P – Positive Parenting Programme previously used by Golley et al. (2007) and Magarey et al. (2011). The Group Lifestyle Triple P programme is a new childhood obesity intervention comprised of three components, nutrition, physical activity and positive parenting, and additional modules and activities aimed at parents of overweight and obese children. The new 12 week programme was used by West et al. (2010) in a RCT involving 101 families with overweight 4 to 11 year old children. Families were randomised to either the intervention condition or the 12 week WLC group. The 12 week programme consisted of nine 90 minute group sessions and three 20 minute telephone sessions. The primary measure was change in BMI z-score measured pre- and post-intervention and at 12 month follow-up.

The intervention was associated with a significant decrease in mean BMI z-score from baseline to 12 weeks (-0.11, SD 0.43, $p<0.001$) when compared with the WLC group. This change was improved at the 12 month follow-up (-0.19, SD 0.46, $p<0.001$). The authors' report that at the 12 month follow-up assessment one third of the children had achieved a clinically significant reduction in BMI z-score and three children had achieved a healthy body size.

The results of this study add to the evidence concerning the importance of parental involvement in the treatment of childhood obesity. The study included only families who had self-referred, suggesting they were motivated to make changes. This might have influenced the results in a positive way compared to the results that might be seen with a mixed group where some have self-referred and some referred in, and may affect the generalisability of the results. The intervention was delivered across a range of settings including a clinic, teaching hospital and schools. However, it was delivered by the same practitioner across all settings. Accordingly, this means the intervention was not tested for delivery by a diverse range of practitioners and therapist effects were unable to be identified. This would need to occur if the intervention was to be scaled up to enable are greater number of families to access the programme.

4.4.2.5 The HIKCUPS Study

The HIKCUPS (Hunter and Illawarra Kids Challenge Using Parent Support) study was a 3-arm parallel group RCT designed to be conducted in community venues to maximise accessibility for participants (Okely et al. 2010). The three intervention arms were: a dietary modification programme aimed at parents (Diet), a physical activity skill development programme aimed at children (Activity) and a combination of the two programmes (Diet + Activity). Each intervention consisted of three components; 10 weekly two hour face-to-face group sessions, a weekly homework component and three telephone calls at monthly intervals following completion of the 10 week programme. To be eligible for inclusion into the study children had to be 5.5 to 9.9 years of age, classified as overweight or obese (using IOTF cut off points) but with a BMI z-score of < 4.0 and pre-pubertal. One hundred and sixty-five children were randomised to one of the three intervention groups and completed the baseline assessment. The primary outcome measure was change in BMI z-score at 6 and 12 months after baseline.

All three groups significantly reduced their BMI z-score at 6 months (Diet: -0.31, 95% CI: -0.39 to -0.22; Activity: -0.16, 95% CI: -0.24 to -0.09; Diet + Activity: -0.31, 95% CI: -0.38 to -0.24; $p<0.001$), and these reductions were maintained at 12 months (Diet: -0.39, 95% CI: -0.51 to -0.27; Activity: -0.17, 95% CI: -0.28 to -0.06; Diet + Activity: -0.32, 95% CI: -0.42 to -0.22; $p<0.001$). Tests of the 6 month to 12 month differences for all groups were non-significant. Participants in the Diet group and Diet + Activity group had a greater reduction in BMI z-score compared with the Activity group. The retention rates for the Activity group were lower at 1 year follow-up compared with the other groups; (Diet = 71%, Activity = 52%, Diet + Activity = 72%). It was unclear why this had occurred, however, the authors suggest that because parents were not directly involved in the programme they may have been less committed to encourage their child to attend.

Collins et al. (2011) reported the results of a 24 month post-baseline follow-up assessment of the HIKCUPS participants. All groups had maintained their significant reduction in BMI z-score at 24 months (Diet: -0.35, 95% CI: -0.48 to -0.22; Activity:

-0.19, 95% CI: -0.30 to -0.07; Diet + Activity: -0.24, 95% CI: -0.35 to -0.13; $p<0.001$). There was a between-group difference for BMI z-score at 24 months with the greatest difference being the reduction for the Diet group compared with the Activity group (-0.17, 95% CI: -0.34 to 0.01).

The results show the two programmes which included the diet component delivered to parents resulted in a better reduction in BMI z-score than the child only activity group. This suggests the parents were key agents of change for the intervention, and parental involvement in childhood obesity treatment programmes is essential. The authors suggest the inclusion of parental behaviour change strategies such as goal setting, role modelling and positive reinforcement may have resulted in parents taking greater responsibility to achieve changes at home which resulted in a reduction in energy intake. The authors also noted the greater beneficial effects in BMI z-score reduction seen in this study compared to studies such as McCallum et al. (2007) and Hughes et al. (2008). They propose this enhanced effect may be due to the higher number of face-to-face intervention contact hours used in the HIKCUPS study, the presence of a programme for children and the intervention being delivered in a community setting. Limitations of the study include the lack of a no treatment control group which would have enabled the results to be generalised to all obese children. The participants were mainly middle-class English speakers so it is not possible to generalise the results to those from other socioeconomic groups. In addition, the activity programme was designed for the specific age range of the children so if the programme was to be delivered to a wider age range of children this aspect would need to be tested.

4.4.3 Treatment interventions delivered in the USA

4.4.3.1 The Yale Bright Bodies Weight Management Programme

Savoye et al. (2007 and 2011) reported the results of the Bright Bodies programme, a family-based, intensive lifestyle intervention that has been specifically tailored for the needs of inner-city minority children. The RCT evaluated the programme compared to routine care at the Yale Pediatric Obesity Clinic. Children were eligible for inclusion if they had a BMI above the 95th percentile based on the Centres for Disease Control and Prevention growth chart, were aged between 8 and 16 years and were English-

speaking. Two hundred and nine children were randomised in a ratio of 2:1 into either the Bright Bodies programme or the control group seen every six months. The Bright Bodies programme was delivered at a local school and consisted of twice weekly sessions for six months and then fortnightly sessions for six months. During the first six months the participants took part in two 50 minute exercise classes and one nutrition / behaviour modification session per week. The primary outcome measure was change in BMI z-score at six, twelve and twenty-four months post-baseline.

The intervention group significantly reduced their BMI z-score at 6 months (-0.16, 95% CI: -0.20 to -0.13), and these reductions were maintained at 12 months (-0.21, 95% CI: -0.25 to -0.17) and 24 months (-0.20, 95% CI: -0.25 to -0.16). The between group differences were significant (p<0.0001) at each time point; 6 months: -0.18 (95% CI: -0.24 to -0.12), 12 months: -0.23 (95% CI: -0.29 to -0.16) and 24 months: -0.16 (95% CI: -0.23 to -0.09).

The results show the beneficial effects on BMI z-score were sustained at 24 months even though the intervention phase of the programme stopped at 12 months. The differences between the groups were greater at 12 months than at 24 months, and further results at 36 months and beyond would be required to assess if the beneficial effects were able to be maintained into adulthood, or whether the participants BMI z-score would continue to revert back to their starting point. The research team performed an intention-to-treat analysis and were working with ethnically diverse, low incomes families so the achievements at 24 months should be noted. The attrition rate was quite high and this could have been due to the intensive nature of the intervention and the substantial time commitment required (twice weekly meetings for 6 months). However, it might be this type of population requires an intensive approach to achieve and maintain long-term changes. In accordance with this, the HIKCUPS study (Okely et al. 2010) demonstrated that a higher number of face-to-face contact hours produced better results than other studies with a lower intervention ‘dose’.

4.4.3.2 Project STORY

Families living in underserved rural areas were targeted for weight management support in Project STORY (Janicke et al. 2008). Ninety-three families participated in

the 3-arm RCT which comprised a behavioural family-based intervention (FB), a behavioural parent-only intervention (PO) and a waiting list control group (WLC). Children were eligible for inclusion if they were between 8 and 14 years of age and had a BMI greater than the 85th percentile for age and sex. The programmes were delivered at the Co-operative Extension Service office in participating counties. The intervention was 4 months in duration and families were invited for a follow-up assessment 10 months after the start of the intervention. Families received $50 for completing each assessment. For both intervention groups weekly group sessions, lasting ninety minutes, were held for the first 8 weeks and then biweekly for the next 8 weeks. In the FB group parents and children participated in simultaneous but separate groups. The primary outcome measure was change in BMI z-score at 4 months and 10 months post-baseline.

The results at 4 months post-baseline demonstrate a significant decrease in mean BMI z-score in the PO group compared with the WLC group (0.127, 95% CI: 0.027 to 0.226, $p<0.05$). No significant difference was seen between the FB and WLC groups (0.065, 95% CI: -0.027 to 0.158, $p=0.16$), and the PO and FB groups (0.061, 95% CI: -0.039 to 0.162, $p=0.23$). At 10 month follow-up both the PO (0.115, 95% CI: 0.003 to 0.220, $p=0.04$) and FB (0.136, 95% CI: 0.018 to 0.254, $p=0.03$) showed significantly greater improvement in mean weight status relative to the WLC group. Children in the PO group reduced their BMI z-score by 0.090 (± 0.039) units and those in the FB group by 0.115 (± 0.046) units. Differences between the PO and FB groups were not significant.

At 10 month follow-up the PO group achieved maintenance of the intervention effects, and the FB group showed improvements compared with the control group. Additional analysis showed a greater beneficial effect for children under the age of 11 in the PO group, and over the age of 11 in the FB group. These results differ from those reported by Golan, Kaufman and Shahar (2006) who reported a greater decrease in child weight status in the PO intervention compared with the FB intervention at 6 month post-assessment and 12 month follow-up. The authors of Project STORY suggest one potential reason for this difference might be that the study used daily self-monitoring and goal-setting, whereas the Golan, Kaufman and Shahar study (2006) did not include these behavioural strategies. The reduction in BMI z-scores demonstrates that both the PO and FB interventions are effective. The FB group continued to improve their

weight status at the 10 month follow-up whilst the PO group showed partial maintenance of intervention effects. This may be due to the children in the FB group using the skills they had been coached in to continue with weight reduction, whilst the PO group were relying on the parents to drive changes at home. Longer-term follow-up of the participants is required to determine whether the improvements in weight status are maintained.

4.5 Implications of recent RCTs to the present study

The studies under review were conducted in both clinical and community settings. It is interesting to compare these settings as both have their benefits and the model for the current research used a community setting. Potential advantages of a clinical setting are that interventions, such as the SCOTT RCT (Hughes et al. 2008) and LEAP (McCallum et al. 2007) were delivered on a one-to-one basis permitting an individualised approach tailored to the families needs. Other interventions delivered in a clinical setting such as FBBT (Croker et al. 2011) and the PEACH RCT (Golley et al. (2007), used a group approach. The clinical setting offers a medicalised environment which may help the group focus on the reason they are attending and encourage participants to view the intervention as an important part of their family's care. Advantages of a community setting for the delivery of primarily group-based interventions are accessibility and the ability to target specific communities, with the intervention held locally in a leisure centre, community centre or schools (Sacher et al. (2010), Bryant et al. (2011) and Coppins et al. 2011)). These types of settings often have the equipment and space to offer a variety of physical activity opportunities compared with clinical settings. Furthermore, delivery in the community offers an alternative approach which de-medicalises childhood obesity, providing treatment in a less imposing environment. This less formal environment could mean families feel more relaxed and, therefore, open to discussion regarding their behaviours and the changes they are trying to achieve.

Comparison of the results of change in BMI z-score of the clinical and community based studies shows that overall the studies showing better effectiveness were conducted in a community setting and provided a programme for both parents and children. Analysis of the community interventions showed a group approach to delivery

of the intervention was used in all cases with WATCH IT (Bryant et al. 2011) also including one-to-one appointments. Interventions such as MEND (Sacher et al. 2010) and Project STORY (Janicke et al. 2008) included group sessions for parents and children together, and group sessions for parents and children separately. The group parent-only sessions were used to raise awareness in, and coach parents', skills in behavioural change strategies and positive parenting. The group child-only sessions were used for physical activity.

The interventions aimed at parents only, Triple P (Golley et al. 2007), PEACH (Magarey et al. 2011) and Group Lifestyle Triple P (West et al. 2010), were designed for the parents of younger children (aged 4-11 years). Studies including children from 10 years old used a family-based (children and parents both participating) model. For example, in Project STORY (Janicke et al. 2008) children in the family-based intervention who were 11 years and older experienced an approximately 50% greater decrease in weight status relative to the older children in the parent-only treatment group. This suggests interventions targeting children who are 11 years and above may prove more effective when delivered to both the parents and children, as the children may be able to support and even implement the knowledge and skills taught in the sessions.

Further analysis of the detail given in the papers shows the community based interventions for children and parents focused on behavioural strategies to modify diet, nutrition education and encouraged changes in physical activity patterns and reduction in sedentary behaviours. The community based model, including group sessions for children and parents, and a separate parent only workshop, incorporating the themes given above was used by the programme presented in this thesis. At the time of development of the intervention, (see chapter 5), this design fitted the requirements highlighted by the needs assessment and was suitable for the setting available for programme delivery.

The design of the intervention also required a decision regarding the inclusion of a control group. Only the LEAP trial (McCallum et al. 2007) used a traditional no treatment control group. Most studies (n=7) used a WLC design of 3 to 12 months, three studies had a control group who underwent routine clinical care and two studies

compared intervention groups and had no control group. The results from Coppins et al. (2011) suggest for greatest effect participants need to start in the intervention as soon as possible after recruitment. This has implications for the use of RCTs and other study designs using a waiting list. Magarey et al. (2011) felt strongly about not using a control group stating, 'We believed that, having recruited obese children and their families, offering no intervention or wait-listing for 2 years was unethical and, furthermore, likely to result in substantial attrition in the control group with substantial threats to internal validity' (p. 220). However, in accordance with a number of the community based studies described in this section a WLC group was decided upon for this study. The studies described above used a WLC group of 3 to 12 months in duration. For this study the participants in the control group were asked to remain on the waiting list for a three month period only because the PCT hosting and funding the study did not want families to wait any longer than was necessary to start the programme. A study by Rudolf et al. (2006) reported a mean increase in BMI z-score of 0.2 over a 3 to 6 month period in children on the waiting list for treatment, indicating that children on a waiting list with no intervention may continue to increase their BMI. As the resources were available to accommodate the families after three months on the waiting list this became the protocol for the intervention.

4.6 Summary

This chapter has given an overview of the literature concerning the treatment of childhood obesity. The systematic reviews and the original literature review highlighted the factors that were considered in the development of the programme. These included targeting lifestyle behaviours to change diet, increase physical activity levels, decrease sedentary behaviours and the inclusion of BCTs. Evidence presented in these studies informed the intervention evaluated in the current research study to focus on a family-based programme including both children and parents. The next chapter (chapter 5), gives an overview of the protocol used to develop the intervention and describes how the programme was developed.

The review of RCTs conducted between 2007 and 2011 provides an understanding of the components of similar interventions to the programme developed in this research, and gives an insight into their effectiveness. These studies were chosen as they are

RCTs offering different modes of delivery in different settings to different groups. The implications of these studies on the design of the present study are considered including the setting, delivery of group or individual sessions, targeting parents only or family-based and the use of a control group. Section 8.6 provides a comparison of the change in children's BMI z-score from the results of the RCT reported in this thesis with the RCTs described in section 4.4.1 that were delivered in the UK.

Chapter 5 Methodology for intervention development

5.1 Introduction

Interventions developed within obesity management need to be both structured and evidence-based (SIGN 2010, NICE 2006). This chapter commences by considering a range of frameworks which were considered for the development of this programme and continues by explaining why Intervention Mapping (IM) was chosen. An overview of the IM protocol is given by examining the six steps encompassing the process. The chapter continues by documenting the results of each step of the protocol which gives the reader an understanding of how theories, evidence and user views have been integrated and developed into an intervention. Following this the evaluation methods for the intervention are discussed. The chapter concludes with a description of the final intervention and analysis of the behaviour change techniques included in the programme.

5.2 Development of the Y W8? programme

This family-based weight management programme was developed using the IM protocol. At the time of development in 2005 there was little research on designing effective family-based models utilizing existing behavioural theories which could be implemented in primary care in the UK (SIGN 2010). During the early stages of development the NICE published guidelines on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). This document highlighted there was little UK-based evidence on the effectiveness of multi-component interventions among key at-risk groups (for example, young children and families). The guidelines also emphasized the need for appropriately designed research evaluating multi-component interventions to manage obesity in primary care, and that interventions should be undertaken in 'real world' everyday clinical and non-clinical settings. Locally, the prevention and treatment of obesity in children was a key focus for Telford and Wrekin PCT. Local funders and decision makers required an evidence-based, theoretically grounded intervention that could be developed using local stakeholders and implemented in routine service immediately. Consequently the development of this intervention addressed an evidence gap and was timely.

5.2.1 Intervention design

Interventions are commonly designed without evidence of having gone through a process of matching the intervention features to the behavioural target, the target population and the context in which the intervention will be delivered (Michie, van Stralen and West 2011). They are often based on implicit commonsense models of behaviour (Michie et al. 2009a). The guidance from the UK MRC on developing and evaluating complex interventions (Craig et al. 2008), advocates drawing on theory in intervention design but does not specify how to select and apply theory (Michie et al. 2005). Thus, a protocol incorporating a systematic method of gathering evidence about the nature of the behaviour to be changed, selecting and applying theory during the design phase, and evaluating the effectiveness of the intervention needed to be chosen.

A number of approaches and models were considered for the development of this programme. Local decision makers required stakeholders to be involved in the development of the programme and an evidence-based and theoretically grounded intervention which could be implemented into NHS routine service immediately. Many approaches were discarded due to a lack of user involvement in the planning stages, being a less rigorous approach with no theoretical input, or the framework not being dynamic to respond to new information and new demands from organisations. Those given serious consideration were the ATM (antecedent, target, measurement) approach for developing logic models, the Interactive Domain Model (IDM) of best practices in health promotion and the Intervention Mapping (IM) approach. These three approaches are described below and their strengths and weaknesses in terms of this development are discussed.

5.2.1.1 ATM approach for developing logic models

The ATM approach is a systematic three step process for creating logic models which are often used as a methodology for programme design in public services (Renger and Hurley 2006). A logic model sets out how an intervention is understood or intended to produce particular results (Rogers 2005), and often comprises a set of linked causal statements

about how it is intended to work in a logical flow. Renger and Titcomb (2002) acknowledged that logic models are based strongly in theory and consist of complex elements that are difficult for practitioners to understand and utilise. The theory included in the programme is conceptual and its inclusion in the programme's actions is supposed to achieve the outcomes intended. Theory, in this context, is developed as an articulation of causal assumptions; it is seldom pre-existing theories, such as self-regulation theories. However, evaluation programmes have sometimes found that the theory stated by programme developers is not operationalized sufficiently to explain how a programme is intended to work. The ATM approach was developed to improve the effectiveness of how logic models are applied in practice. The three step process incorporates an understanding of the causes of the problem (antecedent conditions), linking the components of proposed strategies to the antecedent conditions (targeting) and assessing the effect of intervention strategies on the targeted antecedent condition (measurement) (Renger and Titcomb 2002).

Page, Parker and Renger (2009) used the ATM approach to identify and redefine programme activities when addressing the shortage of health care professionals choosing to practice in rural and underserved areas in the USA. They undertook twenty stakeholder interviews to determine key reasons why students' were not entering into the health profession (the antecedent conditions). A total of 44 antecedent conditions were identified and were then prioritised by importance. Existing activities were then linked and theoretically grouped together. The resulting list was modified and new activities were developed to address the prioritised antecedent conditions (targeting). For example, one activity involved inviting guest speakers to address potential student health professionals. Originally the guest speaker wrote their own speech but after following the ATM approach speakers were given some suggestions and guidance of content to include in their speech which related to the prioritised antecedent conditions. The practitioners evaluated the number of individuals choosing to become health care professionals to assess the effectiveness of the strategies they used to target the antecedent conditions (measurement). However, whilst following the process allowed activities to be developed and modified to address the identified antecedent conditions, the approach did not direct users to map theories to the strategies to develop understanding and effectiveness further.

The ATM approach results in a visual representation of programme elements similar to that produced by using the PRECEDE-PROCEED model (Green and Kreuter 2005). Other authors have commented that the ATM approach results in a single logic model in a static systems approach, whereas a preferable model would result in a network of logic models that describe a larger system (Urban and Trochim 2009). Furthermore, for the current programme of research, it was essential during the development of the programme to consider the long-term future of the intervention, and the ATM model does not explicitly address how to plan for sustainability (Urban and Trochim 2009). It was imperative this was given attention as the initial funding was only for three years and the future delivery of the intervention would depend upon its success in the initial three years. The results would also give information regarding the feasibility and affordability of plans for implementation and for its sustainability in routine services. All these factors were important for this research, hence, the ATM approach was not considered further.

5.2.1.2 The Interactive Domain Model (IDM) of best practices in health promotion

The IDM is a comprehensive best practices approach to preventing illness and enhancing health for people working in health promotion, public health and population health (Kahan and Goodstadt 2001). The IDM Best Practices Framework is the practical application of the IDM. The framework has the domains; underpinnings (health promotion values and goals) and understanding of the environment and practice on the vertical axis, and across the horizontal axis are the four steps of the framework; diagnosis, planning, implementation and evaluation (Kahan and Goodstadt 2005a). IDM has been used to develop a range of health promotion programmes including a health coaching initiative, a healthy child development programme for low income children and a chlamydia screening uptake social marketing campaign (Kahan, Groulx and Wong 2007).

The IDM aims to increase awareness of health promotion best practices. 'It is a comprehensive guidelines approach which emphasizes the importance of consistency between practice and a number of decision-making factors ranging from values and goals to theories, evidence and understanding of the environment' (Kahan and Goodstadt 2005a: 3). It uses evidence based research and community consultation in the early steps to inform programme planning and development. However, the version of the framework

available at the time of developing this programme was unsuitable as a high level of direction would have been required from the methodology experts. This would have been impractical due to financial and time constraints. Kahan, Groulx and Wong (2007) reported they required a high level of support including training to use the framework as it was difficult to understand the categories and the concepts were difficult to understand. Due to these factors the IDM framework was rejected.

5.2.1.3 Intervention Mapping (IM)

The IM protocol was chosen for a number of reasons. Firstly, the use of a structured, evidence-based approach to intervention development and evaluation has been recommended within obesity management (SIGN 2010, NICE 2006). The IM protocol provides this as programme developers are required to work their way through the protocol gathering evidence and selecting theory-based intervention methods to be included in the final programme. Also, Johnston and Dixon (2008) noted there is insufficient attention given to analysing the nature of behaviour as the starting point of behaviour change interventions, and IM is a notable exception to this. In addition, since the mid-1990's there has been a move for health promoters to incorporate the ideas and reflect the needs of lay people who otherwise merely figure as the 'objects' of professional health promotion programmes (Katz, Peberdy and Douglas 2000). Engaging local service recipients at the planning stage assists in ensuring the intervention meets the needs of the local population and should form part of the needs assessment. Step 1 of the IM protocol offers this element and this proved critical for the development of this intervention. Further, the use of this protocol ensured the intervention was grounded in theory, and the most recent Cochrane Review of *Interventions for Treating Obesity in Children* recommended that high quality research that considers psychological determinants for behaviour change and cost-effective programmes for primary and community care is required (Oude Luttikhuis et al. 2009). IM also requires the developer to consider the design of the evaluation throughout all the steps of the process. This should ensure the evaluation is developed alongside the intervention and is firmly integrated in the final programme. Thus, the IM protocol was an appropriate method for intervention development.

Intervention Mapping (IM) was introduced by Bartholomew and colleagues (Bartholomew et al. 2006) with the purpose of providing health promotion programme planners with a structured process for the development of theory- and evidence-based programmes. Since this research commenced, within the field of obesity IM has been used to develop interventions for the prevention of obesity in children, adolescents and adults, and weight management in overweight adults. Within these topics it has been used for a variety of programmes including large scale programmes across different European countries and smaller school-based interventions within a city. A benefit of the protocol is its adaptability to various sizes and complexity of interventions. Aside from this research, it has not been used to develop a programme to treat childhood obesity.

Within Europe the protocol has been used for a number of large scale studies designed to prevent childhood obesity (De Henauw et al. 2011, Verbestel et al. 2011, Kremers et al. 2005, Kwak et al. 2006, Singh et al. 2006). In all these large multi-country studies, whilst enabling theory-informed and evidence-based interventions to be developed, the authors of these studies identified some problems with using the IM protocol at this level. De Henauw et al. (2011) and Verbestel et al. (2011) reported the development of the Identification and prevention of dietary- and lifestyle-induced health effects in children and infants (IDEFICS) community oriented intervention programme (COIP) study, which is one of the largest childhood obesity prevention programmes in Europe. The study aimed to prevent overweight and obesity in children in different European countries by developing a multi-component intervention targeting lifestyle and behaviour determinants at the community, school, household and individual level. The authors chose not to follow the protocol strictly due to time constraints, and the multi-level and multi-behavioural approach. They reduced the complexity by only creating matrices of change objectives at the individual level instead of for each level of intervention planning (individual, school, family and community). The authors observed that however complex the intervention being developed, when using the IM protocol time, budget and human resources should be considered carefully (Verbestel et al. 2011).

Kremers et al. (2005) and Kwak et al. (2006) described the use of IM to develop the Netherlands Heart Foundation – Netherlands research programme weight gain prevention (NHF-NRG). The programme aimed to prevent weight gain in different target groups by

focusing on the balance between food consumption and physical activity. Similarly to Verbestel et al. (2011), the developers of the NHF-NRG did not completely apply the protocol as they chose not to create the matrices of learning and change objectives. This decision was made due to the complexity of weight gain prevention and the authors though it unpractical to create learning and change objectives for all the identified determinants. They chose, instead, to guide the specification of the performance objectives according to self-regulation theory and implementation theory. Despite using this modified version of IM, Kwak et al. (2006) advocate the use of this systematic approach as it enables developers to produce thorough documentation of the effective methods and successful strategies and, they suggest, should eventually lead to more cost-efficiency with regard to tackling obesity.

Another study forming part of the NHF-NRG project was the Dutch Obesity Intervention in Teenagers (NRG-DOiT) (Singh et al. 2006). This research team used the IM protocol to develop two components of an intervention programme; an individual classroom based intervention and an environmental intervention. Due to time constraints, Singh et al. (2006) also used a shortened version of the IM protocol and reduced the number and complexity of the matrices created. The authors reflected on the process describing it as 'complex' and 'time consuming' (p.316), but felt following the protocol and applying theories would improve the likelihood of effectiveness of interventions, and felt positively towards the feedback loops built into the process as these would assure the programme matched the needs of the target population.

In a smaller study based in the UK the IM protocol was used by Lloyd et al. (2011) in the development of the Healthy Lifestyles Programme (HeLP). HeLP was a childhood obesity prevention programme based in schools. The intervention targeted three health behaviours; reduction of the consumption of sweetened fizzy drinks, increase in the proportion of healthy snacks consumed and reduction in screen time. The authors reported the process was time consuming, and found the tools did not provide enough guidance on how to organise the behaviour change techniques and the delivery methods into a sequenced framework. To overcome this, the research team applied a process model of behaviour change, the Health Action Process Model (HAPA). Despite needing to take this further step to develop a coherent intervention, the authors praised the IM

protocol for the manner in which the approach ensured the BCTs and delivery methods linked directly to the performance objectives and their associated determinants. Due to this each technique included had a clear purpose and increased the potential of the intervention achieving its outcomes.

A common criticism of the IM approach is how time consuming it is, which also affects the budget required and the staff time needed to complete the process. In addition, when developing multi-level and multi-behavioural programmes a number of authors (De Henauw et al. 2011, Verbestel et al. 2011, Kremers et al. 2005, Kwak et al. 2006, Singh et al. 2006) have chosen to use a shortened version of the protocol to decrease the time required for the process and reduce the complexity of the outputs. Despite these negative factors, developers praise the systematic approach of the IM protocol as it allows theories, BCTs and delivery methods to be linked to performance objectives in a coherent framework. This process creates thorough documentation, assures the intervention is matched to the needs of the target population and improves the likelihood of effectiveness of the intervention.

5.3 Overview of Intervention Mapping

Bartholomew et al. (2011) suggest that IM is an iterative process encompassing six key steps (box 5.1). Each step comprises a number of tasks which create intervention matrixes which are guides for the subsequent step. The process produces a framework that links the determinants of particular health behaviours with performance objectives and strategies to be incorporated into the programme design.

Box 5.1: Steps of the Intervention Mapping Protocol

(1) Needs assessment
(2) Creating matrices of proximal programme objectives
(3) Selecting theory-based intervention methods and practical strategies
(4) Designing and organising a programme
(5) Specifying adoption and implementation plans
(6) Generating programme evaluation plans

(Bartholomew et al. 2011)

5.3.1 Step 1: Needs assessment

The first step of IM involves the following tasks; formation of a steering group, conducting a needs assessment, developing the evaluation plan, analysis of local community capacity and resources and establishing programme outcomes. These tasks are important to ensure the planner understands the health problem being targeted, its behavioural and environmental causes and the community in which the intervention is to be set.

The steering group should include both professionals and laypeople that have an interest in the health problem, potential programme participants and those who will be involved in the design, delivery and sustainability of the project. The group membership should evolve over the course of the planning process as different aspects of the intervention are focussed on.

The needs assessment should be conducted using the PRECEDE model from the PRECEDE-PROCEED model (Predisposing, Reinforcing, and Enabling Constructs in Educational Diagnosis and Evaluation – Policy, Regulatory, and Organisational Constructs in Educational and Environmental Development) (Green and Kreuter 2005). The PRECEDE model is a framework for the process of systematic development and evaluation of health education programs and the IM steps are complementary to the planning phases of this model. The model is used to identify quality of life, health, behaviour and environmental determinants for the at-risk population and to decide on priorities.

Developers are required to begin developing the evaluation plan at this stage. The results of the PRECEDE-PROCEED model can be used to determine the measures that should be considered. The evaluation plan should be developed during each stage of the IM approach to ensure the evaluation is embedded in the final programme and the correct measures are used to be able to evaluate the effectiveness of the intervention. This is in accordance with the updated MRC guidance (Craig et al. 2008) which encourages developers to consider the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works.

The next task is to undertake an analysis of the capacity and resources of the local community. This could include facilities and accommodation to host the project, funding for employment of staff and staff training, local expertise and knowledge for designing the programme, and funding or sponsorship for materials and resources for the project. This analysis ensures the intervention is built on existing strengths of the community in which it will be implemented.

The final task is to establish programme outcomes related to the health or quality-of-life indicators identified in the needs assessment. Analysis is carried out of the determinants of the risk behaviours identified by carrying out a literature review. Conclusions after the literature review may cause revision of some of the provisional determinants or additional determinants to be included.

The product of Step 1 should be a list of personal and environmental factors linked to the health problem being targeted which could be addressed within the intervention. The determinants should then be prioritised in accordance with the analysis of capacity and resources. This results in a list of determinants which have the capacity to be changed within the scope of the intervention, and these lead to a selection of desired programme outcomes.

5.3.2 Step 2: Creating matrices of proximal programme objectives

Step 2 provides the foundation for the intervention by specifying who and what will change as a result of the intervention (Detaille et al. 2010). This step requires a number of tasks to be undertaken that result in a set of matrices of change objectives which document the changes that need to occur in the behavioural or environmental conditions to improve the health and quality of life outcomes identified in step 1 (Bartholomew et al. 2006).

The first task is to document the health-related behaviours and environmental conditions to be changed. This list should show the most important behaviours of the at-risk group that are causally related to the health problem and, therefore, shows the health-promoting or risk-reducing behaviours and healthy environmental conditions that will be the focus of the

intervention. The second task is to write performance objectives for each of the programmes' behavioural and environmental outcomes. The third task specifies the personal and external determinants of the health behaviour and environmental conditions. Finally, a set of matrices of change objectives that combine performance objectives for personal and environmental determinants is created.

5.3.3 Step 3: Selecting theory-based intervention methods and practical strategies

In Step 3, useful theory-based and evidence-based learning and behavioural change strategies that are applicable to the change objectives are selected (Bartholomew et al. 2006). This should result in preliminary ideas for the intervention which can be reviewed by members of the steering group. Once agreed, practical strategies should be selected or designed for delivering the intervention methods.

5.3.4 Step 4: Designing and organising a programme

The methods and practical strategies are translated into intervention materials in Step 4 of the protocol, and the programme is designed. This task requires consultation with intended participants and programme deliverers to ensure their opinions and preferences influence programme content and materials. As recommended by the updated MRC guidance (Craig et al. 2008), the intervention should then be piloted with intended deliverers and recipients.

5.3.5 Step 5: Specifying adoption and implementation plans

The focus of Step 5 is programme adoption and implementation plans, including consideration of programme sustainability. The product of this step is a detailed plan for accomplishing programme adoption and implementation by influencing behaviour of individuals or groups who will make decisions about the future delivery of the programme (Bartholomew et al. 2006).

5.3.6 Step 6: Generating programme evaluation plans

In the final step of IM the evaluation plan should be finalised. This plan should have begun in the needs assessment and developed alongside the intervention. The outcome and process evaluation will allow planners to determine whether the decisions made during each step of development were correct, and whether the intervention was successful in changing the health problem being targeted.

5.4 Application of IM to the Y W8? Programme

5.4.1 Step 1: Needs assessment

To complete the first step of the IM process a steering group was formed, a needs assessment utilising focus groups and interviews was conducted, a literature review was carried out and local community capacity and resources were analysed.

5.4.1.1 Formation of a steering group

A steering group of local professionals was formed to enable partnerships to be formed with key representatives from multidisciplinary services. The initial membership of the steering group included the programme developer, obesity service manager, paediatric dietician, paediatrician, school nurse, health intelligence manager, GP, school teacher, child psychologist, representative from Child and Adolescent Mental Health Services and representative from leisure services at the local council. The group met monthly for the first 6 months and bi-monthly for the next year. Once the intervention had been piloted and the main study had commenced the group membership changed to become a working group of those involved in the delivery of the programme.

5.4.1.2 Needs assessment

For the needs assessment, data regarding the prevalence of childhood obesity was sought at a number of levels. National targets and statistics were gathered to gain an understanding of the magnitude of the obesity epidemic in the UK (DH 2004b). Reports

and papers offering guidance and recommendations for the development of the programme e.g. NICE (2006), SIGN (2010) were also identified. Regional data was sourced to understand the local situation compared to the rest of the country, and a local needs assessment was performed using data from the NCMP (The NHS Information Centre, Lifestyle Statistics 2009a and Jotangia et al. 2005). This data has been presented in chapter 3.

5.4.1.3 Focus groups and interviews

To establish facilitators and barriers to change, and to ascertain potential programme participant's views on the design of a weight management programme, focus groups and interviews with parents were conducted (see sections 5.4.1.4, 5.4.1.5 and 5.4.1.6). Although Bartholomew et al. suggest both professionals and laypeople should be included on the steering group the protocol was amended at this stage to incorporate focus groups and interviews as a means of obtaining this valuable information in both a sensitive and pragmatic way.

Focus groups took place in six local secondary schools to investigate the children's perceptions and practices related to food choices, nutrition knowledge, attitude and beliefs regarding healthy eating and exercise. Their views on how a weight management service for children and their families would look were also sought. Focus groups were planned, conducted and evaluated based on methods used by the local Children and Young People's Active Involvement Service and two texts (Krueger and Casey 2000, Porcellato, Dugdill and Springett 2002). During the focus groups interactive activities were used to engage with the pupil's and gain their knowledge and views regarding a range of subjects. The detail regarding the activities used is shown in the weekly discussion guides (appendices 5, 6, 7 and 8). Schools were purposively sampled throughout the borough to ensure pupils from a variety of socio economic backgrounds were included. Pupils were randomly selected from a list of the year group. Children were not selected based on their weight status as the groups were designed to explore the age groups knowledge, beliefs and attitudes to nutrition and exercise; gathering a broad dataset on children's opinions was important. Additionally, selecting only children who were overweight or obese would have singled out individuals in the school setting and could have resulted in bullying or

unnecessary attention. Prior to commencing the focus group parental and child consent was obtained. Research and development approval was gained from Telford and Wrekin PCT and Coventry University for the focus groups (appendices 3 and 4).

Forty-seven pupils of both genders from years 7, 8 and 9 attended a set of focus groups for four consecutive weeks during their normal Personal Social Health Education lesson time. Each focus group was conducted by a trained facilitator and an assistant facilitator took notes. All the facilitators were employees of Telford and Wrekin PCT and worked in the Health Improvement Service. The weekly discussion guides are presented in appendices 5, 6, 7 and 8. All focus groups were taped, transcribed and thematically analysed using a long-table approach (Krueger and Casey 2000). The results are presented in appendices 9 and 10.

Semi-structured interviews were conducted with six parents of potential programme participants. The parents who were interviewed had approached the local School Nursing Service for support with their child's weight and the School Nursing Service sought their consent prior to the author contacting them. The interviews were used to identify the factors the parents regarded as contributing to their child's weight issue, explore the barriers to themselves, their child and their families changing to a healthier lifestyle, and the elements they would regard important in a family-based weight management programme. All interviewees completed an interview consent form prior to the interview taking place (appendix 11). Ethical approval was not required for this piece of work. The interview schedule is shown in appendix 12. Interviews were taped, transcribed and thematically analysed using a long-table approach (Krueger and Casey 2000). The results are presented in appendices 13 and 14.

5.4.1.4 Findings from the focus groups

Themes regarding the facilitators and barriers to change from the focus groups are shown in box 5.2.

Box 5.2: Themes from the focus groups regarding facilitators and barriers to change

- Low consumption of fruit and vegetables
- Only half the children reported eating breakfast
- When given a choice children consumed high fat and high sugar foods
- Most children ate meals in front of the television
- Children knew the key healthy eating messages
- Pupils had a good understanding of the health consequences of unhealthy food
- Children did not feel at risk of long-term conditions because of their age
- Pupils understood that sedentary behaviour was unhealthy
- Boys reported doing more team or competitive sports
- Girls were more likely to report walking and exercising alone
- Pupils knew the recommended amount of exercise they should take each day

Themes included the low amounts of fruit and vegetables consumed, the food and drink choices the children make at meal and snack times and the location of meals. Children preferred to eat foods high in fat and / or high in sugar because they preferred them and they viewed them as convenient and cheap. Key health messages were also discussed, for example '5 a day' and the recommended amount of daily physical activity children should be taking. The pupils had a good understanding of the key health messages and a good understanding of the health consequences of unhealthy food. A table of quotes illustrating these themes is shown in appendix 9.

5.4.1.5 Findings from the semi-structured interviews with parents of overweight and obese children

Themes regarding the facilitators and barriers to change from the interviews with parents are shown in box 5.3.

Box 5.3: Themes from the interviews with parents regarding facilitators and barriers to change

- Children eating too much 'junk' food
- Continually snacking on high fat or high sugar foods
- High sugar drinks
- Portion sizes too big
- Will not eat vegetables
- Never has breakfast
- Unhealthy school dinners
- Meals were convenience foods
- Not enough time to cook meals from fresh ingredients
- Other family members are not supportive of changes
- Family members might sabotage efforts
- Child spends too much time on the computer / watching TV
- Should be more PE lessons in school
- Need more local activities for children that are free or low-cost
- Do not like letting their child out in the neighbourhood
- Parents do not exercise regularly due to lack of time

Parents expressed a number of factors they regarded as contributing to their child's weight issue. Regarding their child's energy intake the themes that emerged included eating too much 'junk' food, continually snacking on high fat or high sugar foods, consumption of high sugar drinks and large portion sizes. Parents also had concerns their child would not eat vegetables, never has breakfast and chooses unhealthy school dinners. When exploring barriers to making healthy changes parents admitted many of the meals at home were convenience foods as they felt they did not have enough time to cook meals from fresh ingredients. Parents also recognised that other family members would not be supportive of making changes and some family members, such as grandparents, might try to sabotage efforts as they would feel sorry for the child.

A consistent theme across parents was that their child spent too much time on the computer or watching television. Most parents felt there should be more physical education lessons in school and would like there to be more local activities for children that are free or low-cost. Some parents commented they did not like letting their child out to play in their neighbourhood due to safety concerns. The parents admitted they did not take enough exercise, the main reason for this being a lack of time. A table of quotes illustrating these themes is shown in appendix 13.

5.4.1.6 Findings influencing the design and organisation of the programme

Ideas for the design and organisation of the weight management programme were gathered from both the focus groups and interviews with parents and were used in step 4 of the IM protocol to design and organise the programme. To achieve this, in the final week of the focus groups the pupils were asked to design a weight management programme by producing a poster to illustrate their main ideas. The key themes identified by these posters are shown in box 5.4.

Box 5.4: Themes from the focus groups regarding the design of the programme

- It should be located outside of school
- Children's parents should be involved
- Children should have the opportunity to try new activities
- Participants should be able to take part in regular exercise sessions
- Participants should have the chance to try new foods
- Families should learn how to cook
- The programme should run after school in the early evening
- Chance to meet new people and make new friends
- Chance to taste healthy foods
- It must be fun
- Staff should not be judgmental

The key themes identified from the interviews with parents are shown in box 5.5.

Box 5.5: Themes from the interviews regarding the design of the programme

- Parents need to be involved
- Should run after school or in the early evening
- Parents should be able to improve their cooking skills
- Practical ideas for making changes at home
- Improve child's confidence
- Opportunity to make new friends
- Course should be free
- Discussions about topics such as comfort eating and bullying

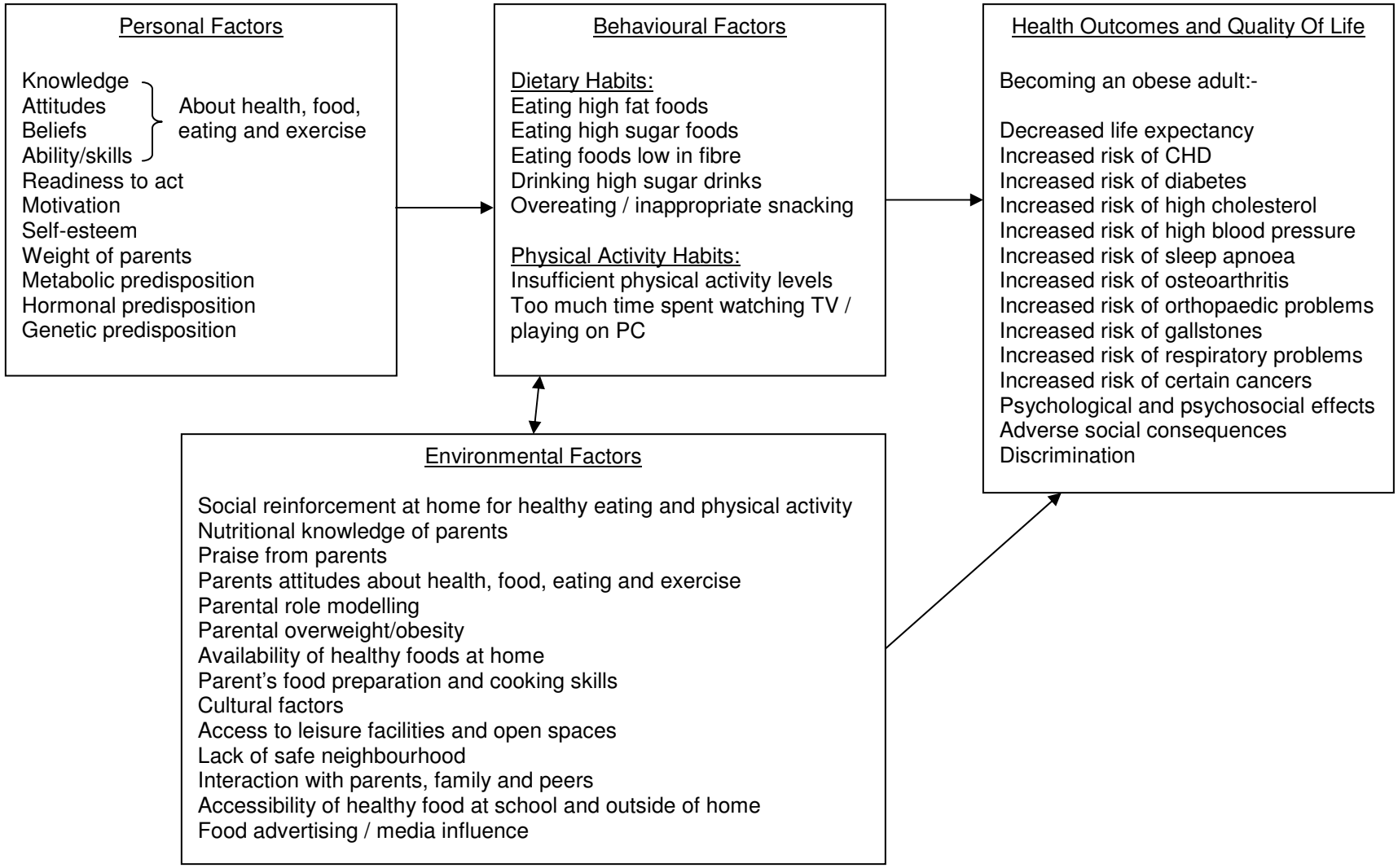
Pupils felt the programme should be located outside of school as they thought children would not want to go back to the school once their timetabled day had finished. They also had concerns that if children were going back into school and were seen by others they might be bullied or teased. Both pupils in the focus group and parents who were interviewed felt the parents of the children attending the weight management programme should be involved so the family could work together to achieve change. It was suggested the programme should run after school or early in the evening to accommodate those parents who work. Participants of the focus group viewed activity as a key part of the programme, and the programme should offer children the chance to get fit and have fun whilst exercising. Healthy eating was also a key theme identified with focus group participants and parents highlighting the need for cooking skills and the chance to try healthy foods. Many pupils thought the programme would need to be fun so the families would want to keep attending, and it would be a good opportunity for children to meet new people and make new friends. Parents who were interviewed felt it would be important they were provided with practical ideas for making changes at home and were supported with these changes. There was also agreement that the programme should be designed to improve children's confidence, and parents would like information and discussion about topics such as comfort eating and bullying. All interviewees requested that the programme should be free. Tables of quotes illustrating these themes are shown in appendices 10 and 14.

5.4.1.7 Literature review

An initial literature review was conducted in 2005 to examine the relevant research in the field and to identify the factors that should be considered in the development of a successful treatment programme. The review demonstrated the previous successful use of a multi-component approach for the treatment of childhood obesity. Many of the published studies had been conducted in the USA and Israel; with few reports from the UK in community-based settings which could be implemented in primary care (Oude Luttikhuis et al. 2009). An updated literature review is documented in chapter 4.

Information gathered from the steering group, focus groups, interviews with parents, needs assessment and literature review were collated using the PRECEDE model, (Green and Kreuter 2005) as shown in figure 5.1 below.

Figure 5.1 PRECEDE model for the childhood obesity programme



5.4.1.8 Analysis of local community capacity and resources

The analysis of community capacity included the identification of a local higher education establishment with new sports facilities and suitable teaching rooms where the project could be located. Three years of funding was gained from Sport England and the Big Lottery for the development of the project, employment and training of staff and a feasibility study. The local PCT had a budget for printing of materials and resources and members of the steering group offered their expertise and knowledge throughout development.

5.4.2 Step 2: Creating matrices of proximal programme objectives

After the review of the literature and guidance the steering group agreed the overall desired outcome of the intervention was to decrease participant's BMI. Although a contested measure, BMI was chosen as it is recommended in clinical guidelines for the NHS in England. It is also a simple anthropometric measure which is low-cost, easy to use and acceptable to participants. In particular for this study, BMI can be collected by non-clinical staff and provides a quick, non-invasive method to collect, monitor and provide feedback on weight status. The results can also be easily converted to change in percentage BMI, BMI z-score and BMI centile. To achieve a decrease in BMI the specific outcomes of reducing total energy intake and increasing energy output were defined and two subgroups were identified that could be targeted; children and parents. For each of these outcomes and subgroups, performance objectives were decided upon. The performance objectives were divided into behavioural objectives, which referred to the obese child, and environmental objectives, which referred to the parents. The behavioural and environmental change objectives are given in boxes 5.6 and 5.7.

Box 5.6: Behavioural Change Objectives (Children)

- Reduce total energy intake:
  - Decrease consumption of high fat foods
  - Increase intake of fruit and vegetables to 5 portions a day
  - Decrease intake of high sugar foods
  - Decrease intake of high sugar drinks
  - Decrease intake of processed foods
  - Have a healthy breakfast everyday
  - Increase nutritional knowledge
  - Self-monitor dietary intake
  - Try new foods

- Increase energy output:
  - Increase daily physical activity levels to recommended amounts
  - Try new activities
  - Limit time spent in sedentary activities

Box 5.7: Environmental Change Objectives (Parents)

- Reduce total energy intake:
  - Decrease availability of high fat foods in the home
  - Increase availability of fruit and vegetables in the home
  - Decrease availability of high sugar foods in the home
  - Decrease availability of high sugar drinks in the home
  - Decrease child's intake of processed foods
  - Encourage child to have a healthy breakfast
  - Increase nutritional knowledge
  - Plan and structure mealtimes
  - Serve child controlled portions
  - Monitor child's energy intake
  - Read food labels
  - Try new foods

- Increase energy output:
  - Increase child's daily physical activity levels to recommended amounts
  - Assist child in limiting time spent in sedentary activities

Finally, the objectives were specified in terms of the actual change required in the theoretical determinants of behaviour. In order to achieve this, each performance objective was analysed separately and appropriate theoretical determinants were identified

which would be deemed useful in changing each performance objective. The output of this process was a matrix of change objectives detailing what will be targeted in the intervention. Table 5.1 shows an example matrix of change for the performance objective; 'decrease consumption of high fat foods'. The matrices for all the performance objectives can be found in appendices 15 - 18.

Table 5.1. Example matrix of change for the change objective; 'decrease consumption of high fat foods'

Performance Objectives (Children)	Personal Determinants					External Determinants	
	Attitudes	Knowledge	Skills and Self-efficacy	Outcome Expectation	Perceived Social Norms	Cues	Reinforcement
PO.1.1 Decrease consumption of high fat foods	A.1.1a Feel positive about making changes to dietary fat intake A.1.1b Express positive attitude toward choosing low fat foods	K.1.1a Know the problems of eating a high fat diet K.1.1b Be able to distinguish between low and high fat foods	SE.1.1a Explain to others the problems of eating a high fat diet SE.1.1b Demonstrate ability to distinguish low and high fat foods SE.1.1c Express confidence in ability to recognise low and high fat foods	OE.1.1a Expect to feel healthier after dietary changes OE.1.1b Expect decrease in consumption of high fat foods to help with weight management OE.1.1c Choose low-fat food options	N.1.1a Recognise that others in the group are decreasing intake of high fat foods N.1.1b Recognise that others in the group are choosing low fat options N.1.1c Accept that normal weight children consume less high fat foods N.1.1d Family members decrease high fat food consumption	C.1.1a Parents buy low fat alternatives C.1.1b Parents serve less high fat foods C.1.1c Low fat foods are available for snacks C.1.1d Parent and family members choose low fat options	R.1.1a Parent praises child for eating less high fat foods R.1.1b Parent and family members decrease intake of high fat foods R.1.1c Parent praises child for choosing low fat options R.1.1d Parent and family members choose low fat options

5.4.3 Step 3: Selecting theory-based intervention methods and practical strategies

The next task was to select appropriate theoretically derived methods to change behaviour and translate these into practical strategies suitable for the intervention. Findings from the focus groups and interviews, and information gained from the literature review were used to decide which strategies were suitable for inclusion in the programme. Table 5.2 shows an example matrix presenting practical strategies, theoretical base and intervention methods for the performance objective; 'decrease consumption of high fat food'. The matrices showing all the change objectives and practical strategies can be found in appendices 19 and 20.

Table 5.2. Example matrix showing theoretical methods and practical strategies for performance objective; 'decrease consumption of high fat food'

Change Objectives	Practical strategy	Theoretical Base	Method
SE.1.1b, SE.1.1c	Skill training	Increasing self-efficacy – Social cognitive theory (Bandura 1986)	Workshop activities Food and activity diaries Physical activity sessions
N.1.1a, N.1.1b, N.1.1d, R.1.1b, R.1.1d	Role modeling	Increasing self-efficacy – Social cognitive theory (Bandura 1997)	Workshop discussions and activities Parent only workshops
A.1.1a, A.1.1b	Persuasive communication	Attitude change – Elaboration likelihood model (Petty, Barden and Wheeler 2002, Petty and Cacioppo 1986) Persuasion communication matrix (McGuire 1985) Social cognitive theory (Bandura 1986)	Workshop discussions and activities Physical activity sessions
OE.1.1a, OE.1.1b, C.1.1a, C.1.1b, C.1.1c , N.1.1c	Cues to action	Goal-related theories Health Belief model (Janz and Becker 1984)	Workshop discussions and activities Physical activity sessions
C.1.1d, R.1.1a, R.1.1c, R.1.1d	Feedback and reinforcement	Increasing self-efficacy - Social cognitive theory (Bandura 1997)	Parent only workshops
K.1.1a, K.1.1b	Active learning	Increase knowledge - Persuasion communication matrix (McGuire 1985) Elaboration likelihood model (Petty, Barden and Wheeler 2002, Petty and Cacioppo 1986) Social cognitive theory (Bandura 1986)	Workshop discussions and activities Physical activity sessions
K.1.1a, SE.1.1a	Awareness raising	Transtheoretical model (TTM) (Prochaska, Redding and Evers 2002)	Workshop discussions and activities Physical activity sessions
K1.1b, OE.1.1c,	Self-monitoring	Self-regulation theory (Kanfer 1970, Karoly 1993)	Food and activity diaries

5.4.4 Step 4: Designing and organising a programme

Using the information generated from the previous steps the intervention was designed. The programme included the practical strategies identified in step 3, and resources and materials were developed to be user friendly and appropriate for the client group. For example, the weekly handouts used pictures and colour where possible to explain key messages, 'top tips' to summarise key points sections were included and the language used was easily understood.

At this stage a small pilot study was completed with 12 families. The decision to carry out this pilot fits with the updated MRC framework (Craig et al. 2008). Families were referred in by health professionals who were members of the steering group, and the parents who had taken part in the semi-structured interviews attended with their child. The intervention was delivered by the programme developer. The dietitian who had been a member of the steering group attended all group sessions to quality assure the nutritional advice being delivered. At the start and end of the pilot children and parents had their height and weight recorded to calculate BMI centile and BMI, respectively. To measure levels of self-esteem children were asked to complete the Self-Perception Profile for Children (SPPC) with the questionnaire entitled 'What I am Like' (Harter 1985), families completed a food diary and a locally developed Healthy Family Behaviours Questionnaire. At the end of the intervention both children and parents completed a post-programme evaluation. Ethical approval was not applied for this small pilot as it was considered service delivery.

The programme deliverer and participants were asked to provide feedback at the end of each session by using a graffiti wall for the children and a simple questionnaire for the parents. The design and content of the programme was amended at the end of the small pilot. Improvements are shown in table 5.3. Once piloted and reviewed the final aims, structure and content of the programme were agreed by the steering group.

Table 5.3 Improvements made to the Y W8? programme after the small pilot

Issue	Improvement made
Pre- and post-evaluation self-esteem measure	Using a shortened version of the SPPC as the younger children found the full 36-item questionnaire too long to complete successfully
Quizzes at the start of each session	Quizzes were introduced at the start of each session to re-cap previous session content, encourage families to work together and to provide activities for the participants to take part in whilst waiting for all the group to arrive
Shopping session	Developed into a supermarket tour to make it more practical for families
Introduction of a cooking session	Introduced to give families the opportunity to try new foods, develop basic cooking skills and work together to prepare a healthy meal
Introduction of extra weekly physical activity sessions	Extra weekly physical activity sessions were delivered to foster maintenance of activity behaviours and increase motivation to continue with healthy changes
Food diary	The food diary was amended to enable children to record the amount of activity they took part in and the amount of 'screen time' they had

5.4.5 Step 5: Specifying adoption and implementation plans

At this stage the programme manual was written which included session plans and tutor notes for the weekly workshops. Production of the manual was crucial for the successful training of staff to deliver the programme and ensure it was implemented with fidelity. An example week from the Y W8? manual can be found in appendix 44. (The full manual is available from the author on request). In addition, implementation plans were developed which aimed to ensure the programme received future funding from the local PCT. This included ensuring the programme was part of the local Obesity Strategy and the local council's Children's Services Strategy.

5.4.6 Step 6: Generating programme evaluation plans

In the final step of the protocol evaluation plans were confirmed. The MRC framework (Craig et al. 2008) suggests suitable outcome measures should be chosen based on the theoretical understanding of the intervention. They also suggest a process evaluation

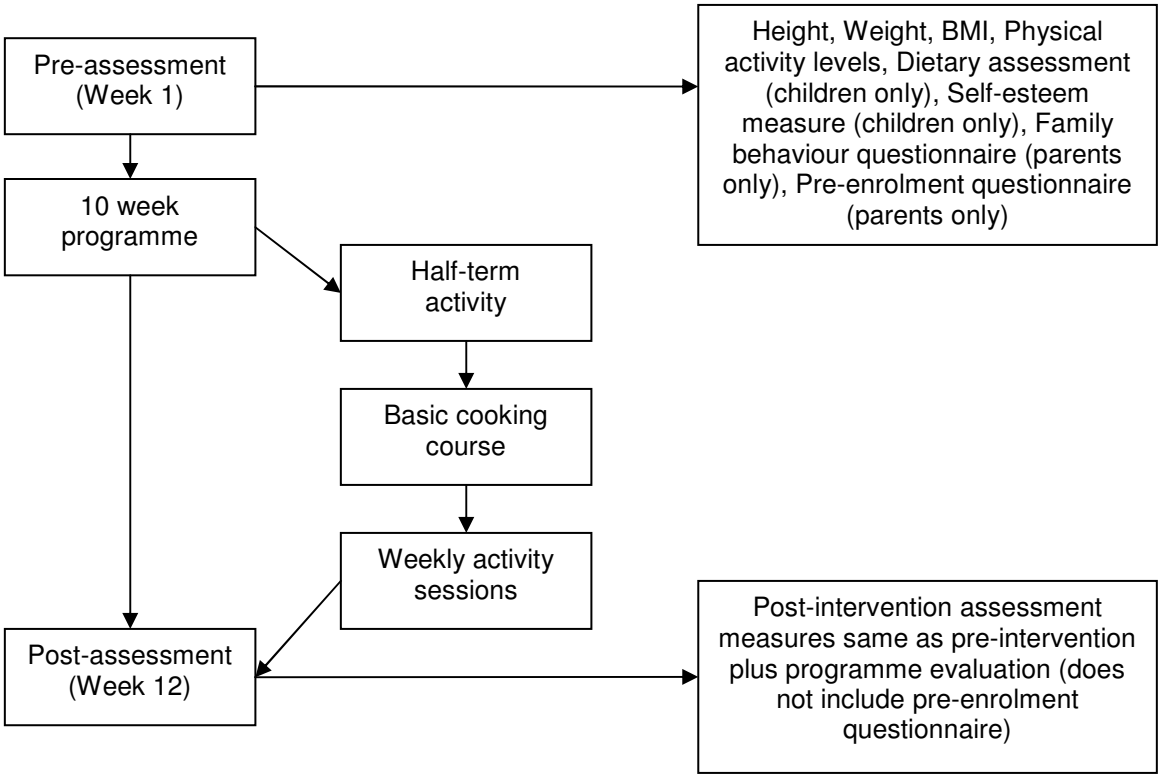
should be carried out to understand the processes by which an intervention has worked or not worked, to assess fidelity and the quality of implementation. For this intervention the evaluation plans included both process and outcome evaluations and a mixed-methods approach to collect both qualitative and quantitative data. This data was collected concurrently and analysed to focus on the degree to which the findings converged to further explore the effectiveness and acceptability of the treatment programme, and measure whether the programme was successful in achieving its desired outcomes. The process of 'triangulation' was used for this with the goals of confirmation and completeness of the data (Begley 1996).

Triangulation is the process of examining an issue using different methods and focusing on the degree to which the findings converge (Denzin 1978). For example, one area where 'triangulation' is beneficial is to see the degree to which the responses to questionnaires and interviews converge around issues such as changes made in the home eating environment and the child's physical activity levels. This type of analysis will enhance the validity of the findings of each data collection method, and lead to greater insight. The benefits of triangulation can include a stronger research design, the qualitative and quantitative data being compared and checked against one another to reach a more valid and reliable conclusion, and each approach can be used together to gain a more in depth complete picture (Jick 1979). Arguments against the use of triangulation include researchers deciding to use triangulation only when inconsistencies between quantitative and qualitative data have emerged; 'when faced with the two sets of data, some researchers find it hard to resist making allusions to the symmetry or otherwise between these findings' (Bryman 2006: 266). This has the potential to bring greater understanding, although there should be a clear rationale for the use of mixed-methods at the outset to ensure that the right data collection methods are used. A mixed-methods approach can also create a vast amount of data to analyse which can be time-consuming and increase expense, whilst requiring increased expertise by the researcher in the various methods (Polit and Hungler 1995).

There were other purposes for using a mixed-methods approach in this study drawn from the detailed typology of Bryman (2006); 'credibility' (i.e. enhancing the integrity of the results), 'utility' (i.e. the research is useful to practitioners and can be applied in local

settings) and 'illustration' (i.e. using qualitative data to illustrate and support findings from the quantitative data) (Bryman 2006). In addition, Pawson and Tilley (2005) suggest using various methods of data collection such as interviews, focus groups and questionnaires, to further understand the context in which the programme operates and to gain a better understanding of how the programme works and for whom. The evaluation measures for the programme are shown in figure 5.2 and the design and measures used in the evaluation are described in chapters 6 and 7.

Figure 5.2 Evaluation measures for the Y W8? Programme



To assure fidelity to the programme content and ensure the intervention was delivered with high quality assurance the staff delivering the programme were required to complete an evaluation sheet at the end of each session (appendix 28). Content that was not covered was documented so it could be included during a future session. The evaluation sheets were reviewed weekly to ensure that by the final group session all the content had been covered correctly, and all questions had been answered.

5.5 Description of final intervention - The Y W8? Programme

The Y W8? programme consisted of a two hour weekly, after-school session for 12 weeks, involving fun and interactive workshops and activity sessions. The programme was delivered by weight loss mentors from the PCTs obesity services team and ran at a local further education college. Children between eight and thirteen years of age and overweight with a BMI >91st percentile when plotted on the UK 1990 National BMI percentile reference charts attended with at least one of their parents or main carers (Pittson and Wallace 2010).

The aims of the Y W8? programme were to:

- Coach parents in the skills to change their children's unhealthy behavioural patterns to healthy ones that promote weight maintenance or modest weight loss
- Increase parents' and children's knowledge of nutrition and a healthy balanced diet
- Help parents modify the family environment to develop healthy lifestyle patterns through practical advice and support
- Give children the opportunity to exercise and increase their confidence to take part in physical activity

5.5.1 Analysis of behaviour change techniques included

Interventions designed to change health behaviours such as healthy eating and physical activity are often complex and comprise many, often interacting, components (Craig et al. 2008). Indeed, Craig et al. (2008) in the MRC guidelines for developing and evaluating complex interventions suggest the most challenging part of evaluating a complex intervention is defining the actual intervention. Reporting of intervention content in published evaluations is often brief and imprecise (Michie et al. 2011a), and limits the possibility of identifying the effective ingredients within interventions (Michie et al. 2009b).

At the time of its use in 2010 the CALO-RE (Coventry, Aberdeen and London – Refined) taxonomy comprised 40 BCTs items shown to have good reliability (Michie et al. 2011a). The taxonomy was a development of the original 26 item taxonomy of BCTs developed by Abraham and Michie (2008) which was seen as a first step towards establishing a common language for intervention designers, reviewers and practitioners to specify the content of behaviour change interventions across two behavioural domains (Abraham and Michie 2008). The new 40 item checklist was more comprehensive, well specified and had clearer labels and definitions with good reliability. The CALO-RE taxonomy and the programme manual were used by the developer to classify the BCTs utilised in the Y W8? programme. The results were checked and verified by a member of staff from ARC HLI. Discrepancies between the two results were highlighted, discussed and a consensus agreed. The results of this process are shown in table 5.4.

Table 5.4 Behaviour change techniques included in the programme

Behavioural change technique	Week 1	Week 2 – Child and Parent session	Week 2 – Parents session	Week 3 – Child and Parent session	Week 3 – Parents session	Week 4 – Child and Parent session	Week 4 – Parents session	Week 5 – Child and Parent session	Week 5 – Parents session	Week 6	Week 7 – Child and Parent session	Week 7 – Parents session	Week 8 – Child and Parent session	Week 8 – Parents session	Week 9– Child and Parent session	Week 9 – Parents session	Week 10 – Child and Parent session	Week 10 – Parents session	Week 11– Child and Parent session	Week 11 – Parents session	Week 12
1. Provide information on consequences of behaviour in general																					
2. Provide information on consequences of behaviour specific to the individual																					
3. Provide information about others' approval																					
4. Provide normative information about others' behaviour																					
5. Goal setting (behaviour)																					
6. Goal setting (outcome)																					
7. Action planning																					
8. Barrier identification / Problem solving																					
9. Set graded tasks																					

Table 5.4 (Cont'd) Behaviour change techniques included in the programme

Behavioural change technique	Week 1	Week 2 – Child and Parent session	Week 2 – Parents session	Week 3 – Child and Parent session	Week 3 – Parents session	Week 4 – Child and Parent session	Week 4 – Parents session	Week 5 – Child and Parent session	Week 5 – Parents session	Week 6	Week 7 – Child and Parent session	Week 7 – Parents session	Week 8 – Child and Parent session	Week 8 – Parents session	Week 9– Child and Parent session	Week 9 – Parents session	Week 10 – Child and Parent session	Week 10 – Parents session	Week 11– Child and Parent session	Week 11 – Parents session	Week 12
10. Prompt review of behavioural goals																					
11. Prompt review of outcome goals																					
12. Provide rewards contingent on effort or progress towards behaviour																					
13. Provide rewards contingent on successful behaviour																					
14. Shaping																					
15. Prompting generalisation of a target behaviour																					
16. Prompt self-monitoring of behaviour																					
17. Prompt self-monitoring of behavioural outcome																					
18. Prompting focus on past success																					

Table 5.4 (Cont'd) Behaviour change techniques included in the programme

Behavioural change technique	Week 1	Week 2 – Child and Parent session	Week 2 – Parents session	Week 3 – Child and Parent session	Week 3 – Parents session	Week 4 – Child and Parent session	Week 4 – Parents session	Week 5 – Child and Parent session	Week 5 – Parents session	Week 6	Week 7 – Child and Parent session	Week 7 – Parents session	Week 8 – Child and Parent session	Week 8 – Parents session	Week 9– Child and Parent session	Week 9 – Parents session	Week 10 – Child and Parent session	Week 10 – Parents session	Week 11– Child and Parent session	Week 11 – Parents session	Week 12
19. Provide feedback on performance																					
20. Provide information on where and when to perform the behaviour																					
21. Provide instruction on how to perform the behaviour																					
22. Model / Demonstrate the behaviour																					
23. Teach to use prompts / cues																					
24. Environmental restructuring																					
25. Agree behavioural contract																					
26. Prompt practice																					
27. Use of follow up prompts																					

Table 5.4 (Cont'd) Behaviour change techniques included in the programme

Behavioural change technique	Week 1	Week 2 – Child and Parent session	Week 2 – Parents session	Week 3 – Child and Parent session	Week 3 – Parents session	Week 4 – Child and Parent session	Week 4 – Parents session	Week 5 – Child and Parent session	Week 5 – Parents session	Week 6	Week 7 – Child and Parent session	Week 7 – Parents session	Week 8 – Child and Parent session	Week 8 – Parents session	Week 9– Child and Parent session	Week 9 – Parents session	Week 10 – Child and Parent session	Week 10 – Parents session	Week 11– Child and Parent session	Week 11 – Parents session	Week 12
28. Facilitate social comparisons																					
29. Plan social support / social change																					
30. Prompt identification as role model / position advocate																					
31. Prompt anticipated regret																					
32. Fear arousal																					
33. Prompt self talk																					
34. Prompt use of imagery																					
35. Relapse prevention / Coping planning																					
36. Stress management																					

Table 5.4 (Cont'd) Behaviour change techniques included in the programme

Behavioural change technique	Week 1	Week 2 – Child and Parent session	Week 2 – Parents session	Week 3 – Child and Parent session	Week 3 – Parents session	Week 4 – Child and Parent session	Week 4 – Parents session	Week 5 – Child and Parent session	Week 5 – Parents session	Week 6	Week 7 – Child and Parent session	Week 7 – Parents session	Week 8 – Child and Parent session	Week 8 – Parents session	Week 9– Child and Parent session	Week 9 – Parents session	Week 10 – Child and Parent session	Week 10 – Parents session	Week 11– Child and Parent session	Week 11 – Parents session	Week 12
37. Emotional control training																					
38. Motivational interviewing																					
39. Time management																					
40. General communication skills training																					

5.6 Explanation of studies in this thesis

Once the programme had been developed and the manual written, a feasibility study was carried out. Haynes discussed the importance of evaluating multi-component interventions and understanding whether the intervention works in everyday practice (Haynes 1999). The updated MRC guidance also recommends including a feasibility and piloting stage in the development of complex interventions (Craig et al. 2008). Hence, the feasibility study was planned to ensure the practical utility of the programme as well as to understand whether it works in line with the assumptions made during the design phase.

The feasibility study was designed as a pragmatic investigation to test programme procedures, such as recruitment and retention, ensure the programme could be delivered within the capacity of the existing weight management team and to test the evaluation methods as recommended by Lancaster, Dodd and Williamson (2004). These authors suggest that 'a well-conducted pilot study, giving a clear list of aims and objectives within a formal framework will encourage methodological rigour, ensure that the work is scientifically valid and publishable, and will lead to higher quality RCTs' (Lancaster, Dodd and Williamson 2004: 307). One hundred and twenty-two children and their families were recruited to the feasibility study. Study design was a simple pre- post-intervention evaluation. The full methods and results for this study are documented in chapter 6.

The second study was designed as a RCT. The MRC guidance (Craig et al. 2008) encourages researchers to consider carefully the evaluation of complex interventions to ensure the results provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works. The guidance advises that randomisation should always be considered when the study is being designed. However, while the RCT is the gold standard for clinical studies of well specified treatments such as medications, there is debate about its role in health promotion research. The WHO European working group on health promotion evaluation documents that RCTs are inappropriate. They state; 'the use of randomized control trials to evaluate health promotion is, in most cases, inappropriate, misleading, and unnecessarily expensive' (WHO Europe 1999: 5). Mackenzie and colleagues (Mackenzie et al. 2010) also argue that RCTs are not always suitable or practical and use the Scottish Government's 'Keep Well' programme as an

example. This multi-component programme aimed to tackle inequalities in cardiovascular morbidity and mortality in Scotland by targeting those at risk of preventable serious ill health by inviting them to attend a health check and then signposting to appropriate interventions and services. The complex programme was not suitable for an RCT for a number of reasons. Standardisation of the reach and engagement strategies was not possible across individual areas as it would have required considerable policy and practice commitment leading to a substantial time delay in delivering the programme. Without this standardisation it was not possible to describe how different approaches affected the target population. In defence of this, Pawson and Tilley (1997) have argued that a standardised approach for a complex programme is misguided and does not enable researchers to ascertain what works for whom in what circumstances. Secondly, the intervention was developed within a complex organisation which was continually adapting and changing. However, the MRC guidelines assume that interventions will reach a point of stability. In the 'Keep Well' programme, independent of the research team, learning between and during the pilots led to practices changing their approaches over time. This learning often occurs in programmes that are implemented in real life rather than within the artificial constraints of an RCT (Mackenzie et al. 2010). Finally, 'Keep Well' was inextricably linked to a policy approach and the MRC guidelines require interventions to be withheld from control populations which is in conflict with this. Within the complex 'Keep Well' programme it would have been very difficult to assure non-contamination of controls as the 'control practices' would have been aware of the programme and may well have utilised it for their patients as they knew it was available.

Rosen et al. (2006) refute the arguments opposed to the use of RCTs and present approaches to overcoming the practical issues involved. They suggest that 'a wisely designed RCT is a far superior evaluation mechanism for answering specific types of questions compared with the evaluation approaches that are currently popular in the health promotion field' (p.1181). The paper also suggests that in order to reverse public health issues such as obesity, studies should be developed with randomised designs that are appropriate for community-based health promotion research.

One hundred and fourteen families were recruited to the RCT. Children were randomised to the intervention group or a waiting list. During initial development of the programme this

study design was thought to be inappropriate by local commissioners as it would lead to unnecessary delays in families commencing the programme. However, once the feasibility study began, and referral numbers increased, it became apparent that the use of a waiting list would be required and, hence, the use of an RCT would be possible. The local PCT supported the study design in the knowledge that some participants would be required to wait prior to starting the intervention, and the local ethics committee also granted approval for the study design and methods. The full methods and results for this study are documented in chapter 7.

5.7 Evaluation of the IM approach

The application of the IM methodology for the development of this intervention resulted in an evidence-based programme informed by users' requirements. The literature review highlighted the IM protocol had not been used previously to develop a childhood obesity treatment programme, and the protocol provided a useful tool to map the path from needs assessment to the developed programme. Following the protocol also ensured there was systematic documentation of the products at each stage of the development, and allowed the researcher the opportunity to carefully consider each decision in the development, implementation and evaluation of the new programme.

The main strengths of using the IM protocol for this research were the structured approach to the application of theory and the level of user involvement, which was greater than in other similar programmes. Working within public funding constraints, including shifting financial priorities, reducing budgets and a need to develop interventions quickly in response to identified need, programme planners often move from a problem definition to intervention development without considering the determinants to be acted upon. Consequently, it is impossible to identify change objectives and appropriate theoretical methods to support behaviour change. The IM approach led the developer through these structured stages gathering evidence and selecting theory-based intervention methods to be included in the final programme.

The formation of the steering group ensured the programme was supported and championed by local stakeholders and enabled a multidisciplinary professional perspective

to be incorporated into programme development. Consultation with potential programme participants through the focus groups and interviews was very important in the development of the intervention and resulted in a truly locally developed programme which the participants felt they had been able to shape and influence. It also ensured the programme was not developed in isolation by 'experts', but incorporated the needs and real life issues facing the families the programme was targeting. In addition, the use of the focus groups led to ideas that would otherwise have been missed. For example, the name of the programme being written in text language (Y W8?) using a mobile phone shaped flier to advertise the intervention, and not using schools as the location.

However, the creation of the matrices of change objectives was a time-consuming process and at times the amount of information that was generated and required analysing was large. Kwak et al. (2006) comment that the IM methodology is typically applied to simple and uni-dimensional behaviours and can become unwieldy when applied to multi-dimensional behaviours such as those involved in weight gain prevention and physical activity. In addition, there was little guidance on how to organise the numerous BCTs and their associated delivery methods into an intervention. Members of the steering group and the researchers experience in the field of delivering adult weight management programmes proved invaluable at this stage.

The final intervention has a similar delivery model to other family-based multi-component interventions currently being delivered (Upton et al. 2009). However, there are a number of key differences between this programme and others which have been included as a result of following the IM protocol. The approach ensured user involvement was very important during development and assisted in defining key aspects such as the location, day, time and activities offered. The strong theoretical rationale also sets this intervention apart from others. Many other programmes in this field have been developed using a less rigorous approach and analysis has shown these to be less effective and less cost-effective (Upton et al. 2009). In addition, the amount of essential and desirable criteria collected as specified in the SEF (Roberts, Cavill and Rutter 2009) developed by the NOO is greater in Y W8? than other similar programmes (Upton et al. 2009). This is important because the SEF lists data collection criteria that can be used to 'support high-quality, consistent evaluation of weight management interventions in order to increase the

evidence base' (p.5). Also, during the post-assessment families are asked to complete an evaluation form. This is recommended by Oude Luttikhuis et al. (2009) and in the MRC framework (Craig et al. 2008) as the use of a comprehensive evaluation form allows qualitative analysis of the views of participants potentially highlighting which elements of the intervention the families found most helpful, and why. Additionally, unlike other programmes Y W8? provides participants with the opportunity to access free family physical activity programmes at local facilities upon completion of the intervention, and families have the chance to participate in healthy eating cooking classes (Pittson and Wallace 2011).

5.8 Summary and conclusions

This chapter demonstrated how and why the IM protocol was used to develop the programme. The overview of IM and results of each stage of the protocol are presented to ensure the programme was grounded in theory and used a structured, evidence-based approach. The final programme is a family-based multi-component intervention which captures the criteria recommended by the SEF and the analysis of BCTs assists further in the understanding of the components included in successful interventions. Through the use of the IM protocol the theoretical basis, BCTs, implementation strategies and evaluation plans were integrated through each step of the process and brought together as a coherent intervention model called the 'Y W8? programme'.

The next chapter describes the results of the first study which was a feasibility study. This study was designed to test programme procedures and evaluation methods, to assess whether an RCT would be feasible, and understand how it should be powered to demonstrate efficacy, as advised in the MRC framework (Craig et al. 2008).

Chapter 6 Study 1 – Feasibility study

6.1 Introduction

This chapter details the feasibility study of the 'Y W8?' childhood obesity treatment programme. The study was designed as a pragmatic investigation to test programme procedures such as recruitment and retention. It was also planned to test the evaluation methods including the basis for power calculations for a subsequent efficacy trial, as recommended by the latest MRC guidance for developing and evaluating complex interventions (Craig et al. 2008). Anderson and Prentice (1999) promoted the use of preliminary studies as they provide information for the planning and justification of RCTs and may lead to changes in the study design. Evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The results of this study informed the design of the intervention and the selection of measures of child and parent outcomes, all of which influenced the delivery of the RCT.

6.2 Aims

The aims of the feasibility study were:

- To evaluate the short-term (3 month post-baseline) effects of the programme on children's BMI z-score and parents BMI
- To evaluate the longer-term (9 month post-baseline) effects of the programme on children's BMI z-score and parents BMI
- To test the feasibility of the operational procedures of the programme
- To explore the acceptability of the programme to families
- To carry out a preliminary test of a number of hypotheses related to improving health behaviours and health status
- To determine the likely size of effect for primary outcome measures in a future efficacy trial

6.3 Methods

6.3.1 Study design

The feasibility study was designed as a simple pre- post-intervention evaluation without a control group to test programme procedures and the evaluation methods. Quantitative data was collected from both children and parents to assess improvements in health behaviours and health status. Qualitative data was also collected in the form of a 'graffiti wall' at the end of each session and interviews at the end of the programme with a number of parents who had completed the programme. The data was collected concurrently and analysed to see the degree to which the quantitative and qualitative findings converge (i.e. triangulation) (Denzin 1978). This concurrent triangulation design 'involves collecting and analysing quantitative and qualitative data concurrently, merging the two sets of data, and using the combination to best understand a research problem'. (Creswell et al. 2003: 376).

6.3.2 Inclusion and exclusion criteria

Children were considered eligible for inclusion if they;

- were between 8 and 13 years of age
- had a BMI >91st percentile when plotted on the UK 1990 National BMI percentile reference charts
- were registered with a GP in Telford
- had at least one parent or carer willing to take part
- spoke a good standard of English
- had no obvious underlying medical cause of obesity
- had no serious co-morbidity or recognised eating disorder

Although the programme could potentially be used with a wider age range of children, it was decided to focus on the 8 to 13 year olds because of the difficulties which arise from combining children of different ages in workshops and physical activity sessions. Children who were overweight (>91st centile) as well as obese (>98th centile) were included. Including children above the 91st centile is consistent with the 'targeted weight

management services' (level 2) care pathways as required in the *Healthy Weight, Healthy Lives: Commissioning weight management services for children and young people* (CSIP NW/Cross-Government Obesity Unit 2008). In addition, the 91st and 98th cut-offs were used to define overweight and obesity as the procedure for the NCMP requires letters to be sent to parents / carers of children who are above the 91st centile. The data from the NCMP could, therefore, be used to inform selection of families in future.

6.3.3 Procedure for recruitment of families

Families were recruited through a number of ways: referral from their GP, school nurse or other health professional, and self-referral in response to local media. On referral families were sent an information pack which contained information on the location, day and times of the programme, the programme content, an application form and a stamped addressed envelope. Families were asked to complete the application form which asked for names, address, telephone number, date of birth, height and weight, and send the form back to confirm their place. On receipt of the application form eligible families were contacted to arrange their pre-assessment and obtain their consent to be included in the intervention. Families who were not eligible were offered other options dependent on their needs. Families who failed to return the application forms were contacted, where possible, to offer advice, support and sign-posting to other services as necessary. All children who met the criteria were offered a place and non-overweight siblings in the age range were invited to attend. Both parents were invited to attend.

6.3.4 Sample size estimation

For the purpose of sample size estimation the primary outcome of this study was change in BMI z-score from baseline to the end of the programme (12 weeks). The study was powered using the data from the GOALS study (Watson et al. 2011). Based on a 1-sided test with a mean difference of -0.09, a significance level of 0.05, a power of 0.80 (as recommended by Cohen 1992) and allowing for a 30% drop-out the sample size required was 40.

6.3.5 Ethical approval

Research and development and ethical approval was received from Telford and Wrekin PCT, Shropshire National Research Ethics Service (NRES) and Coventry University for all aspects of the development and implementation of the programme. (NRES number 06/Q2601/24). (See appendices 21, 22 and 23).

6.3.6 Procedure for delivery of the 'Y W8?' programme

The feasibility study began in April 2006 and finished in December 2009 with eleven programmes being delivered in this time. The 12 week programme was delivered by two weight loss mentors from the PCT's obesity services team (Y W8? mentors), and two trained physical activity instructors. Each programme was delivered by one Y W8? mentor and one activity instructor.

The intervention ran at a local Further Education college on a Friday from 4.30 to 6.30pm. Fridays were chosen as information from the parents' interviews conducted during development of the programme suggested there were less organised activities running on Fridays (e.g. cubs, brownies, swimming lessons). Workshops were held in a large classroom and the activity sessions used the adjoining sports hall and gym. Each two hour session was split into two workshops. During the first hour parents and children had a family healthy eating workshop. The group then split, with the children taking part in an exercise session and the parents having another workshop focused on positive parenting skills and facilitating and sustaining behaviour change. The workshop titles and topics covered in the workshop sessions are shown in table 6.1.

Table 6.1 The Y W8? Programme

	Parent and Child Workshop	Parent Workshop
Week 1	Pre-assessment with Y W8? Mentor	Pre-assessment with Y W8? Mentor
Week 2	Making a Good Start (Healthy breakfasts)	Importance of Role Modeling and Monitoring
Week 3	Keeping the Balance	External and Internal Triggers
Week 4	Eat Right, Stay Bright (Portion control)	Goal Setting and Rewards
Week 5	Fit 4 Life (Importance of physical activity)	Encouraging Healthy Family Behaviour
Week 6	Half-Term – Family activity	Half-Term – Family activity
Week 7	Dump The Junk (Content of unhealthy convenience foods)	Nurturing Your Child's Self-Esteem
Week 8	Stop The Pop (Sugar content of food and drink) (Parent and child workshop held in a supermarket)	Supermarket Savvy (Parent and child workshop held in a supermarket)
Week 9	Hunting 4 Hidden Fat (Fat content of food)	Problem Solving
Week 10	Check Out and Work Out (Programme recap)	The Balancing Act
Week 11	Snack Attack (Healthy snacks, smoothie making and graduation session)	Lapse, Relapse and Collapse
Week 12	Post-assessment with Y W8? Mentor	Post-assessment with Y W8? Mentor

The programme offered a family activity at half-term (week 6). Family activities included a walk up the Wrekin (a large hill within the borough), a visit to a local Victorian town and a visit to a local agricultural college to use their sports facilities and learn about how food is manufactured. After half-term families had the opportunity to take part in a cooking session (Y W8? 2 get cooking), and the programme concluded with a graduation where the children received a certificate to celebrate becoming 'Y W8? graduates'. Families were offered a 9 month post-baseline follow-up appointment to have their height and weight measured to assess the longer-term effectiveness of the programme.

6.3.7 Additional activities offered by the Y W8? Programme

6.3.7.1 Y W8? 2 get cooking

During this session families selected a healthy recipe to prepare from the 'Y W8? 2 Get Cooking' recipe pack they were given at the start of the programme. This session gave families the opportunity to try new foods, develop basic cooking skills and work together to prepare a healthy meal. Families were encouraged to either choose something new to prepare and / or try something they might normally buy as a 'ready meal' and cook it from scratch. The aim was to give families the confidence to try new foods, to demonstrate how they can cook familiar meals with healthy ingredients and to increase their knowledge of the constituents of common foods. Families sat down together to eat the food they had prepared and during this time the children were encouraged to serve themselves and think about portion sizes.

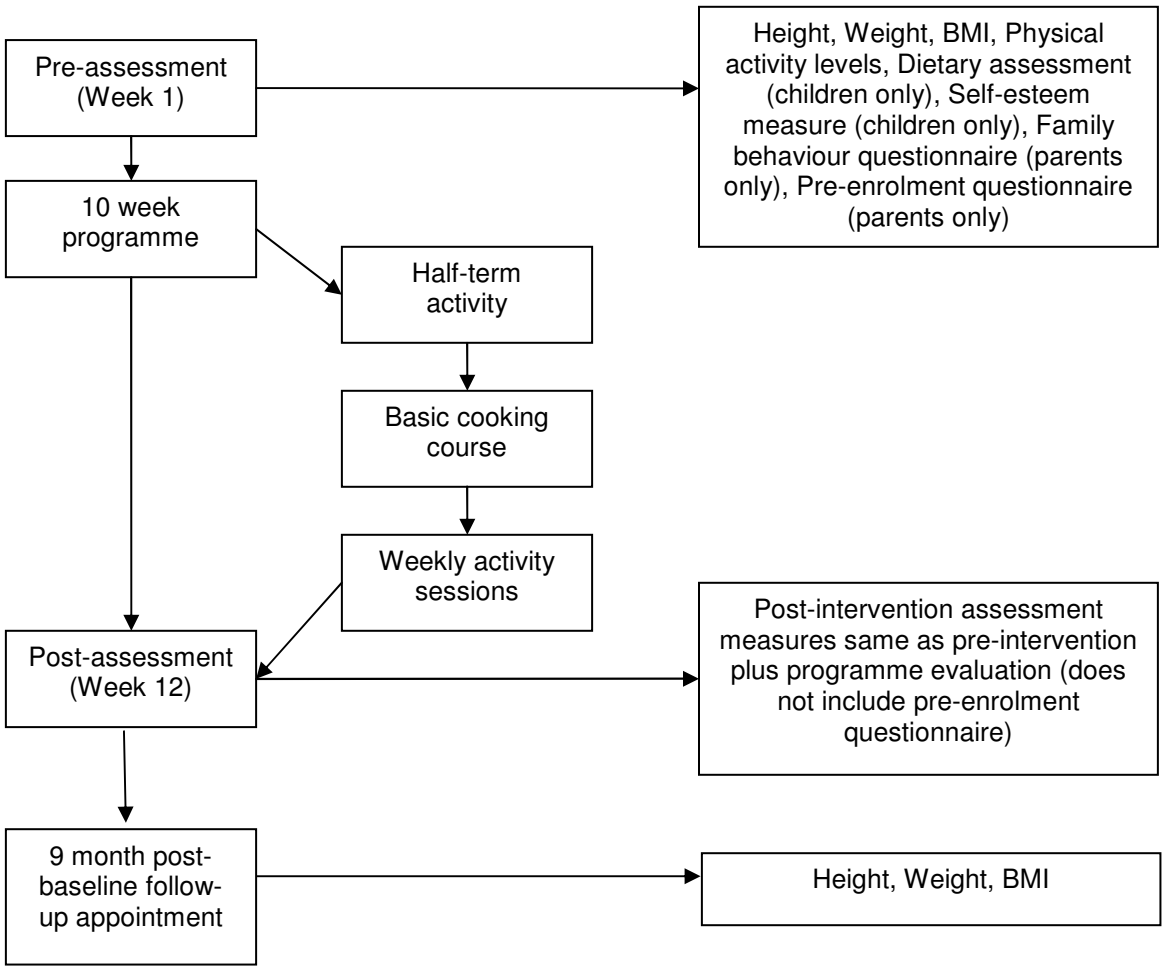
6.3.7.2 Y W8? Activ8!

Families were invited to attend weekly Y W8? Activ8! sessions. During these sessions families on the 12 week programme, and those who had graduated, were able to take part in a structured family activity. The aim of these sessions was to foster maintenance of activity behaviours and increase motivation to continue with healthy changes. During the feasibility study one weekly session was offered in a junior gym.

6.3.8 Outcome evaluation measures

During weeks one and twelve the families met with their Y W8? mentor to have their pre- and post-measurements recorded. The evaluation measures are shown in figure 6.1.

Figure 6.1 Outcome evaluation measures for the feasibility study



6.3.8.1 Measuring BMI

At the pre- and post-assessments children and parents had their height and weight recorded to calculate their BMI. Weight was measured with no shoes and in light clothing, to the nearest 0.1kg using Marsden high capacity digital scales, model MPMS-300

(medically approved version with calibration certificate). Height was measured to the nearest 0.1cm with a Leicester portable stadiometer (Child Growth Foundation, London, UK). Height was measured without shoes, with arms by their side and their head positioned so that the Frankfurt Plane is horizontal (i.e. the ear hole is lined up with the bottom of the eye socket).

BMI was calculated using weight (kg) / height $(m)^2$. For children the BMI was converted into z-scores adjusted for age and sex using an Excel programme from the Child Growth Foundation based on the UK 1990 growth reference curves for BMI (Cole, Freeman and Preece 1995). The BMI centile was also obtained. For parents the BMI was calculated and the classifications used to assess BMI status are shown in table 6.2.

Table 6.2 Classification of adult BMI

Classification	BMI (kg/m^2)
Underweight	< 18.50
Normal range	18.50 – 24.99
Overweight	25.00 – 29.99
Obese class I	30.00 – 34.99
Obese class II	35.00 – 39.99
Obese class III	> 40.00

(Source: WHO 2000)

6.3.8.2 Children's self-esteem

Measuring change in children's self-esteem was a relevant secondary outcome measure for this study as self-esteem was intended to be impacted by the intervention. Problems with self-esteem have been noted in children with weight issues (Walsh-Pierce and Wardle 1997), and the importance of raising self-esteem in weight management interventions has been highlighted (Rees et al. 2009). Previous research has shown significant increases in self-esteem in similar programmes (Epstein et al. 1998). Self-esteem was measured using a shortened version of the Self-Perception Profile for Children (SPPC) with the questionnaire entitled 'What I am Like' (Harter 1985) (appendix 24). This questionnaire is

appropriate for children aged 8 and over. This questionnaire has been used in other similar studies such as, MEND (Sacher et al. 2010), FBBT (Croker et al. 2011) and WATCH IT (Bryant et al. 2011).

The internal consistency reliability of this questionnaire was measured using Cronbach's Alpha(α), with acceptable scores across two samples aged 8 to 11 years from Colorado, USA for the four subscales used in this study: social acceptance (α=0.75), athletic competence (α=0.80 & 0.81), physical appearance (α=0.76 & 0.80) and global self-worth (α=0.78) (Harter 1985). The reliability was also assessed in 4282 Scottish children aged 8 to 15 years, and showed similar reliability (ranging from α=0.72 to 0.83 for the sub-scales) (Hoare et al. 1993).

It was decided to use a shortened version of the questionnaire as during the small pilot study completed during programme development the younger children found the full 36-item questionnaire too long to complete successfully. The full questionnaire uses six sub-scales to measure self-esteem: scholastic competence, social acceptance, athletic competence, physical appearance, behavioural conduct and global self-worth, and each of these has six questions. On review it was decided to remove the sub-scales: scholastic competence, whose items are all school-related and behavioural conduct, which taps the degree to which children like the way they behave. These two scales were removed as they were least relevant to the outcomes of the programme. The four domains that remained in the questionnaire were: social acceptance (the degree at which children feel accepted by peers or feel popular), athletic competence (explore content relevant to sports or outdoor games), physical appearance (measures the degree to which the child is happy with the way they look) and global self-worth (the extent to which the child likes themselves as a person) (Harter 1985). For the six questions in each sub-scale, three questions are worded so the first part reflects high competence and three questions are worded so the first part reflects low competence. The scoring of each question ranged from 1 to 4, with 1 being the least adequate self-judgment and 4 being the most adequate self-judgment.

6.3.8.3 Children's and parents' physical activity measures

Physical activity levels were measured using three selected physical activity questions from the HSE (appendix 25). The questions used in the HSE are parent-reported questions. However, in this study the children were asked to complete the questions themselves. There is currently no 'gold standard' for measuring physical activity (Takken et al. 2003) so the questions were selected based on ease of completion for the age group, and as a performance indicator to see if individuals were achieving the recommended current physical activity targets. The first question asked how important physical activity was to them. The second and third questions assessed if respondents met the CMOs minimum recommendations for physical activity for children (60 minutes every day) and adults (30 minutes on five days of the week). The questions have previously been validated by asking participants in the HSE to wear an Actigraph (accelerometer) and correlating their reported levels of physical activity gathered through the questionnaire against those recorded by the Actigraph. The authors concluded that the questionnaire was both valid and reliable for classifying groups into levels of recommended and vigorous activity, and could be used for monitoring trends over time in population levels of physical activity. The proportion of agreement was 0.70 with Kappa 0.38 (Joint Health Surveys Unit 2007).

6.3.8.4 Children's fruit and vegetable consumption

Children completed a 3 day food diary developed by the PCT's obesity services team – 'Y W8? Nutrition Check' (appendix 26). The Nutrition Check relied on self-reporting from the children and, for younger children, help from the parents to complete. This could make the measure inaccurate. Food diaries also take time and commitment to complete However, the lack of any information on dietary changes has been a criticism made in a systematic review of dietetic interventions in childhood obesity (Collins et al. 2006), so attempting to measure dietary intake should lead to information regarding change in children's diets whilst on the programme.

The diary has space for 7 days of recording but children were asked to complete 3 comprehensive days at a minimum. This also asked where the food or drink was

consumed and included space to record the amount of time spent watching TV or playing on a computer, and the amount of physical activity they took part in. However, the primary aim was to assess the average number of portions of fruit and vegetables consumed over three days. The other information was used to assist the Y W8? mentor in learning more about the lives of the children and give them extra information to use in workshops to assist the families in making changes to a healthy lifestyle. The questionnaire was checked and clarification sought if necessary with parents (e.g. orange juice: was this 'squash' or 'fruit juice'?). In line with national recommendations, fruit juice could only account for one portion of 'fruit and veg' per day, irrespective of the number of times it was drunk. At the start of the study beans and pulses did not count as a 'fruit and veg' portion, however, the guidelines changed during the duration of the study. To maintain consistency beans and pulses were not counted as a 'fruit and veg' portion for this study. Composite foods where it was difficult to determine portions of 'fruit and veg' were also excluded.

6.3.9 Process evaluation measures

A number of process measures were carried out to compliment the outcome evaluation measures and to try and gain further understanding of how and why the intervention worked or did not work. Measures included family's commitment to attend the sessions, the quality of the implementation of the weekly sessions and Y W8? mentors fidelity to the programme content.

6.3.9.1 Register of attendance

A weekly register of attendance was kept for every cohort. To be defined as having completed the programme families had to attend at least seven of the twelve sessions and must have attended the pre- and post-assessment sessions. This cut-off for completion was decided by the programme developer and the Children's Obesity Services Commissioner based on the cut-off points for similar interventions (Sacher et al. 2010, Croker et al. 2011). The number of families dropping out of the programme was recorded and, where possible, their reason for dropping out was obtained.

6.3.9.2 Programme fidelity measures

6.3.9.2.1 Healthy Family Behaviours Questionnaire

Changes in healthy family behaviours were assessed using a locally developed Healthy Family Behaviours Questionnaire completed by the parents (appendix 27). The local questionnaire was developed to reflect the healthy family behaviours being targeted by the programme, and to check whether the content of the programme had been delivered per protocol. Other questionnaires were considered including the Family Eating and Activity Questionnaire from Israel (Golan 1998). However, this was rejected as it required a great deal of 'anglicising'. The locally developed Healthy Family Behaviours Questionnaire comprises 25 statements concerning eating and activity behaviour and the parents were asked to record their answers using a Likert scale; never, hardly ever, some of the time, most of the time or always. The 25 statements were grouped into themes; food and drink, exercise, family behaviour and positive parenting. The questionnaire was piloted on the twelve families who took part in the small pilot conducted during the development of the intervention.

6.3.9.2.2 Y W8? mentor session content evaluation (fidelity) sheet

Each week (excluding weeks 1, 6 and 12), the Y W8? mentor completed a session evaluation sheet feeding back how the session went, if the content was covered and any follow-up required (appendix 28). This ensured that all aspects of the workshops were covered and sections were not missed out. Any content that was not covered was included in a future week and a record kept of when this occurred. The evaluation sheets were reviewed weekly so that by the final group session all the content had been covered correctly.

6.3.9.3 Graffiti wall

At the end of every week a large piece of blank paper was put up on the wall and families were asked to graffiti it with their feedback on the session. Families were encouraged to document comments on the workshops, physical activity sessions and include both

positive and negative remarks. They could write anonymously on the wall and use colour, drawings and words to show their thoughts towards the programme. The graffiti wall was chosen as the participatory method as it provides a creative, informal way of engaging with both children and adults. Children and parents were also offered separate sheets of paper to write on if they did not wish to share their views on the graffiti wall, and they had the opportunity to speak to the Y W8? mentor in private if they wished. By offering these alternatives it was hoped all preferences were catered for and participants had ample opportunity to share both positive and negative comments with the programme developer.

6.3.10 Post-programme evaluation by parents and children

6.3.10.1 Interviews with parents

Semi-structured interviews took place with six parents who had completed the programme. These were carried out at the parent's home just after the end of the programme. The interviews were conducted by the programme developer. Parents were randomly selected from different groups over time. The aim of the interview was to obtain the parents' perceptions of the Y W8? programme and to explore further the areas of the programme the parents found most and least useful in making healthy behaviour changes at home. The interview schedule is shown in appendix 29.

6.3.10.2 Y W8? user evaluations

During the week 12 post-assessment children were asked to complete the Y W8? children's user evaluation and parents the Y W8? parent's user evaluation which was developed by the programme developer (appendices 30 and 31). The evaluation included questions on the length of the programme, ratings of the delivery of workshops, staff knowledge, quality of weekly handouts and changes they had personally made since starting the programme. There were also questions on the content of the workshops and how confident they felt in using the information they had been given.

6.3.10.3 Questionnaire for non-starters / non-completers

Families who failed to complete the programme, (including non-starters), were contacted to investigate the reasons they did not complete the intervention, and to gain feedback on the programme. Questionnaires were completed through either a telephone interview with the Y W8? mentor or sent to the families to complete and return. The questionnaire for non-starters can be found in appendix 32 and questionnaire for non-completers in appendix 33.

6.3.11 Evaluation hypotheses and planned analysis

The primary outcome measure was change in children's BMI *z*-score from baseline to the end of the programme (12 weeks), and at 9 month post-baseline follow-up. This was chosen as the most important outcome the intervention was aimed to change. Intention-to-treat analysis was conducted to evaluate the post-baseline follow-up data. There were also secondary outcomes to measure the success of the childhood obesity treatment programme: improvement in children's self-esteem, increase in children's and parents' physical activity levels, increase in children's fruit and vegetable consumption and improvement in healthy family behaviours. The hypotheses and planned analyses are shown in table 6.3.

Table 6.3 Primary and secondary outcomes with hypotheses to test and planned analyses for the feasibility study

Number	Hypotheses	Outcomes	Planned analyses
Primary outcome			
1	Children who complete the programme will decrease their BMI z-score at 12 weeks	BMI *z*-score	Pre- post test of difference
2	Overweight and obese parents who complete the programme will decrease their BMI		Pre- post test of difference
3	Overweight and obese parents who make the most improvement in their BMI will have children who achieve the greatest improvement in their BMI z-score		Correlation analysis / Multiple regression
4	Children and parents who complete the programme will maintain their improvements in their BMI over the 9 month post-baseline period		Repeated measures ANOVA
Secondary outcomes			
5	Children who complete the programme will increase their self-esteem	Self-esteem	Pre- post test of difference
6	Children who report the greatest increase in self-esteem will show the greatest improvements in their BMI z-score		Correlation analysis / Multiple regression
7	Children who complete the programme will increase their physical activity levels	Self-reported physical activity	Pre- post test of difference
8	Children who increase their activity levels the most will have the greatest improvements in BMI z-score		Correlation analysis / Multiple regression
9	Children who improve how important physical activity is to them the most will have the greatest improvements in BMI z-score		Correlation analysis / Multiple regression
10	Overweight and obese parents who increase their activity levels the most will have the greatest effect on their own BMI		Correlation analysis / Multiple regression
11	Parents who make the most improvements in their activity levels will have children who report the greatest improvements in activity levels also		Correlation analysis / Multiple regression

Table 6.3 (Cont'd) Primary and secondary outcomes with hypotheses to test and planned analyses for the feasibility study

Number	Hypotheses	Outcomes	Planned analyses
12	Children who complete the programme will improve their fruit and vegetable consumption	Self-reported fruit and vegetable consumption	Pre- post test of difference
13	Children who increase the amount of fruit and vegetables they consume the most will have the greatest beneficial effect on their BMI z-score		Correlation analysis / Multiple regression
Process evaluation measure			
14	Families completing the programme will improve their reported healthy family behaviours	Healthy family behaviours	Pre- post test of difference
15	Parents reporting the greatest changes in healthy family behaviours will have the most beneficial effect on their child's BMI z-score		Correlation analysis / Multiple regression
16	Overweight and obese parents reporting the greatest changes in healthy family behaviours will have the greatest improvements in their own BMI		Correlation analysis / Multiple regression

6.4 Results

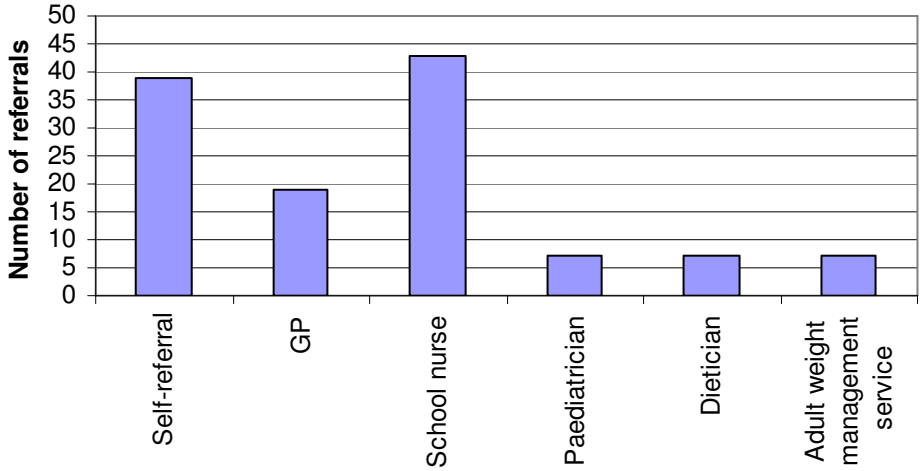
The following terminology is used throughout the results section;

- Non-starters – attended for a pre-assessment but did not start the programme
- Non-completers – did not complete at least 7 of the sessions and/or did not have a post-assessment
- Completers – attended at least 7 out of the 12 sessions including the post-assessment session

6.4.1 Characteristics of participants

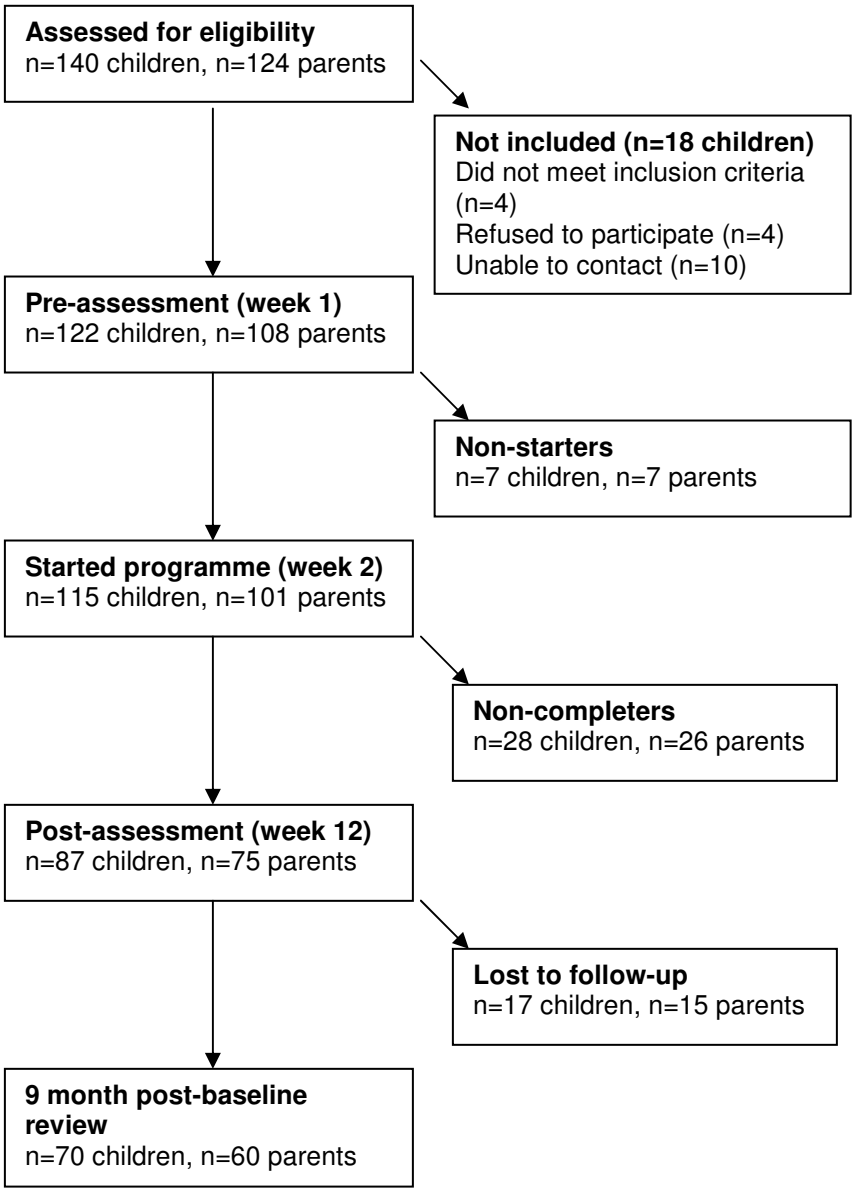
One hundred and forty children were assessed for eligibility with one hundred and twenty-two children and their families being recruited to the feasibility study. Ten overweight or obese siblings also attended but were outside the age range. Only the data for the 122 children is shown. Figure 6.2 displays the number of children attending for a pre-assessment and their recruitment method. (The information for each of the 11 cohorts is shown in appendix 34). Figure 6.3 shows a flow-chart of the families through the study. There are more children than parents at each stage of the flow-chart as some parents brought a number of children.

Figure 6.2 Number of children attending for pre-assessment and recruitment method



'Adult weight management service' (AWMS) refers to those children whose parent was attending one of the adult weight management services offered by the PCT and was referred in from this service. The data shows approximately one-third of families self-referred and the remainder were referred by a health professional.

Figure 6.3 Flow-chart of families through the Y W8? programme feasibility study



6.4.2 Pre-programme assessment data

Table 6.4 shows the baseline characteristics for children and parents who were recruited to the programme and attended for a pre-assessment appointment.

Table 6.4 Baseline characteristics of all children and parents at pre-assessment

		Children (n=122)	Parents (n=107)
Gender	Males	49 (40%)	8 (7%)
	Females	73 (60%)	100 (93%)
Age (years)	Mean (SD)	11.12 (1.58)	40.35 (7.14)
	Range	8.0 – 13.9	26.0 – 61.0
Ethnicity	White	107 (88%)	97 (90%)
	Mixed	5 (4%)	2 (2%)
	Asian	8 (6%)	7 (6%)
	Black	2 (2%)	2 (2%)
BMI classification (children)	Overweight	39 (32%)	
	Obese	83 (68%)	
z-score	Mean (SD)	2.13 (0.38)	
BMI (parents only)*	Not overweight or obese (n)		15 (14%)
	Overweight (n)		31 (29%)
	Obese class I (n)		25 (24%)
	Obese class II (n)		22 (21%)
	Obese class III (n)		13 (12%)

* 1 parent refused to be weighed.

The majority of children were above the 98th centile for BMI and were therefore defined as obese (Cole, Freeman and Preece 1995). In more than a quarter of the families the parent who was attending with the child was overweight, and over half the parents were obese. The table shows that at pre-assessment 60% of the children and 93% of the parents were female. Some 88% of the children and 90% of the adults were White, broadly reflecting the ethnic make-up of Telford (94% white, 6% ethnic minority groups) (Learning Skills Council 2010). (The gender and ethnicity of children and parents at pre-assessment

(week 1), non-starters and non-completers for each of the 11 cohorts is shown in appendix 35).

The baseline characteristics of children and parents who completed, did not start and did not complete the programme are displayed in table 6.5.

Table 6.5 Baseline characteristics of completers v non-starters v non-completers

		Completers	Non-starters	Non-completers
Children (n)		(n=87)	(n=7)	(n=28)
Gender	Males	36 (74%)	4 (8%)	9 (18%)
	Females	51 (70%)	3 (4%)	19 (26%)
Age (years)	Mean (SD)	10.92 (1.54)	10.9 (1.56)	11.79 (1.58)
	Range	8.0 – 13.9	8.8 – 13.5	8.8 – 13.8
Ethnicity	White	77 (71%)	6 (6%)	25 (23%)
	Mixed	1 (25%)	1 (25%)	2 (50%)
	Asian	7 (88%)	0 (0%)	1 (13%)
	Black	2 (100%)	0 (0%)	0 (0%)
BMI classification	Overweight (n)	27 (69%)	2 (5%)	10 (26%)
	Obese (n)	60 (72%)	5 (6%)	18 (22%)
z-score	Mean (SD)	2.13 (0.37)	2.11 (0.3)	2.13 (0.43)
Parents (n)		(n=74)*	(n=7)	(n=26)
Gender	Males	6 (76%)	1 (12%)	1 (12%)
	Females	69 (69%)	6 (6%)	25 (25%)
Age (years)	Mean (SD)	40.49 (7.21)	39.29 (9.20)	40.23 (6.62)
	Range	26 - 61	28 - 54	29 - 52
Ethnicity	White	67 (69%)	6 (6%)	24 (25%)
	Mixed	0 (0%)	1 (50%)	1 (50%)
	Asian	6 (86%)	0 (0%)	1 (14%)
	Black	2 (100%)	0 (0%)	0 (0%)
BMI	Not overweight or obese (n)	9 (60%)	1 (7%)	5 (33%)
	Overweight (n)	21 (68%)	2 (6%)	8 (26%)
	Obese class I (n)	18 (72%)	2 (8%)	5 (20%)
	Obese class II (n)	15 (68%)	1 (5%)	6 (27%)
	Obese class III (n)	11 (84%)	1 (8%)	1 (8%)

* 1 parent refused to be weighed.

One-way ANOVA was used to compare the children's pre-assessment data for completers and non-completers (including non-starters). There was a statistically significant difference at the $p < 0.05$ level between the groups for age at baseline measure: F (1, 120)

= 4.8, p = 0.03, with the completers (M = 10.92, SD = 1.54) being younger than the non-completers (M = 11.61, SD = 1.59). No other differences were highlighted.

6.4.3 Primary outcome results

The measures of body composition for the children who completed and those followed up at 9 months post-baseline are shown in table 6.6, and parent data is displayed in table 6.7.

Table 6.6 Changes in children's measurements from pre-assessment (0 months), post-assessment (3 months) and 9 months post-baseline follow-up (intention-to-treat analysis) for completers

	0 months Mean (SD) (n=87)	3 months Mean (SD) (n=87)	9 months post-baseline Mean (SD) (n=87)	0-3 month change (n=87)		0-9 month change (n=87)	
				Mean (95% CI)	*p* value	Mean (95% CI)	*p* value
BMI z-score	2.13(0.37)	2.01(0.43)	1.97(0.46)	-0.12 (-0.14 to -0.09)	<0.0005	-0.15 (-0.20 to -0.11)	<0.0005
BMI (kg/m^2)	28.63(5.35)	27.76(5.28)	28.11(5.23)	-0.87 (-1.09 to -0.65)	<0.0005	-0.52 (-0.84 to -0.21)	<0.0005
Height (m)	1.49(0.11)	1.51(0.11)	1.53(0.11)	0.015 (0.012 to 0.017)	<0.0005	0.038 (0.033 to 0.043)	<0.0005
Height z-score	0.79(1.03)	0.82(1.04)	0.72(1.01)	0.029 (-0.013 to 0.07)	0.28	-0.075 (-0.152 to 0.003)	0.064
Weight (kg)	64.93(18.55)	64.19(18.40)	66.90(18.7)	-0.74 (-1.27 to -0.21)	0.003	1.97 (1.16 to 2.79)	<0.0005
Weight z-score	2.20(0.64)	2.08(0.69)	2.02(0.70)	-0.126 (-0.15 to -0.10)	<0.0005	-0.18 (-0.22 to -0.14)	<0.0005

Table 6.7 Changes in parent's measurements from pre-assessment (0 months), post-assessment (3 months) and 9 months post-baseline follow-up (intention-to-treat analysis) for completers

	0 months Mean (SD) (n=74)*	3 months Mean (SD) (n=74)*	9 months post-baseline Mean (SD) (n=74)*	0-3 month change (n=74)*		0-9 month change (n=74)*	
				Mean (95% CI)	*p* value	Mean (95% CI)	*p* value
BMI (kg/m^2)	32.74(7.28)	32.30(7.12)	31.88(7.13)	-0.44 (-0.68 to -0.21)	<0.0005	-0.85 (-1.28 to -0.42)	<0.0005
Weight (kg)	88.01(21.64)	86.78(20.95)	85.68(20.95)	-1.23 (-1.88 to -0.58)	<0.0005	-2.33 (-3.49 to -1.16)	<0.0005

* 1 parent refused to be weighed

6.4.3.1 Children's measurements

BMI z-score shows a significant reduction from pre-assessment by -0.12 (95% CI: -0.14 to -0.09, $p < 0.0005$, n=87) to post-assessment (3 months). This difference was improved at 9 month post-baseline review (-0.15, 95% CI: -0.20 to -0.11, $p < 0.0005$, n=87) (table 6.6). This analysis addresses hypotheses 1 and 4. A one-way repeated measures ANOVA comparing scores at pre-assessment, post-assessment and 9 month post-baseline follow-up showed a significant effect for time, Wilks' Lambda = 0.40, F (2, 85) = 64.50, $p < 0.0005$, multivariate partial eta squared = 0.60. The programme did not adversely affect linear growth. Height increased significantly, as would be expected (table 6.6). Height expressed as a z-score did not change significantly.

The level of change which is considered to be clinically significant is a reduction of at least 0.5 BMI z-score (Reinehr and Andler 2004). This reduction is reported to normalize many hormonal and metabolic changes in childhood obesity. The authors do not suggest a timescale over which this change should occur. Table 6.8 shows this level of change was not achieved by any children by the end of the 12 week programme. Analysis of the 9 month post-baseline follow-up data shows that 3 children had achieved this clinically significant reduction.

Table 6.8 Magnitude of change in BMI z-score for each child completing programme from baseline to 12 weeks to assess for clinically significant changes

Change in BMI z-score from baseline	Number of children at post-assessment (n=87)	Number of children at 9 month post-baseline follow-up (n=70)
Increase	4 (5%)	7 (10%)
No change	3 (3%)	1 (1%)
Decrease <0.25	67 (77%)	47 (67%)
Decrease ≥0.25 - <0.5	13 (15%)	12 (17%)
Decrease ≥0.5*	0 (0%)	3 (5%)

* Defined as a clinically significant change (Reinehr and Andler 2004)

An alternative way to explore the change in BMI is to examine whether any children moved between the obese (BMI >98th centile), overweight (BMI >91st to <98th centile) and 'normal'

(BMI <91st centile) categories. This gives useful additional information because a change in -0.5 BMI z-score would not equate to achieving either an 'overweight' or 'normal' weight status in children who were severely obese at baseline; but may do so in children who were overweight or with more modest obesity. Alternatively, children who are close to an overweight or obese cut-off may change category with a lesser reduction in BMI z-score.

Table 6.9 shows 15 children changed obesity category by the end of the 12 week programme; 10 moved from being obese to overweight and 5 moved from being overweight to the 'normal' weight category. At 9 month post-baseline follow-up 9 children had moved from the obese to overweight category and 8 from being overweight to 'normal' weight.

Table 6.9 Change in category of overweight and obesity for children at post-assessment and 9 month post-baseline follow-up

	Post-assessment (n=87)	9 month post-baseline follow-up (n=70)
OBESE at pre-assessment		
Stayed in obese category	50	38
Moved to overweight category	**10**	**9**
Moved to 'normal' weight category	0	0
OVERWEIGHT at pre-assessment		
Moved to obese category	0	0
Stayed in overweight category	22	15
Moved to 'normal' weight category	**5**	**8**

6.4.3.2 Parents' measurements

Parents' significantly reduced their BMI at post-assessment by -0.44 kg/m^2 (95% CI: -0.68 to -0.21, $p < 0.0005$, n=74). This was improved upon at 9 month post-baseline follow-up (-0.85, 95% CI: -1.28 to -0.42, $p < 0.0005$) (table 6.7). This addresses hypothesis 4. A one-way repeated measures ANOVA comparing scores at pre-assessment, post-assessment and 9 month post-baseline follow-up also showed a significant effect for time, Wilks' Lambda = 0.73, $F(2, 72) = 13.55$, $p < 0.0005$, multivariate partial eta squared = 0.27.

Analysis concerning hypothesis 2 showed overweight and obese parents also significantly reduced their BMI at post-assessment by -0.50 kg/m^2 (95% CI: -0.29 to -0.71, $p < 0.0005$, n=65). This was improved upon at 9 month post-baseline follow-up (-0.92, 95% CI: -0.53 to -1.32, $p < 0.0005$, n=65). A one-way repeated measures ANOVA comparing scores at pre-assessment, post-assessment and 9 month post-baseline follow-up also showed a significant effect for time, Wilks' Lambda = 0.70, F (2, 63) = 13.48, $p < 0.0005$, multivariate partial eta squared = 0.3.

6.4.4 Secondary outcome results

6.4.4.1 Children's self-esteem

In response to hypothesis 5, children's self-esteem changed significantly from baseline to 3 months for the four domains measured (table 6.10). The greatest change was seen in the domain 'Athletic competence' (0.37, 95% CI: 0.27 to 0.46, $p < 0.0005$, n=87). The questionnaire was not administered at 9 month post-baseline follow-up.

Table 6.10 Change in children's self-esteem scores from pre-intervention assessment (0 months) to post-intervention assessment (3 months) using the shortened SPPC

	0 months Mean (SD) (n=87)	3 months Mean (SD) (n=87)	0-3 month change (n=87)	
			Mean (95% CI)	*p* value
Social acceptance	2.54(0.81)	2.86(0.83)	0.32 (0.21 to 0.44)	<0.0005
Athletic competence	2.19(0.81)	2.56(0.77)	0.37 (0.27 to 0.46)	<0.0005
Physical appearance	2.01(0.67)	2.30(0.63)	0.29 (0.19 to 0.40)	<0.0005
Global self-worth	2.57(0.82)	2.88(0.68)	0.31 (0.21 to 0.41)	<0.0005

For hypothesis 6, the relationship between change in average self-esteem score and the four self-esteem domains and change in BMI z-score was investigated using Pearson product-moment correlation coefficient. A small positive correlation was found between change in BMI z-score with change in average self-esteem score($r=0.24$, $n=87$, $p < 0.05$) and change in global self-worth ($r=0.283$, $n=87$, $p < 0.05$), with increases in scores associated with improvements in BMI z-score. No significant correlations were seen between change in BMI z-score and change in social acceptance score, change in athletic competence score and change in physical appearance score (table 6.11).

Table 6.11 Correlation between change in self-esteem scores and BMI z-score

	Pearson Correlation (n=87)	*p* value
Change in average self-esteem score	0.24	0.012
Change in social acceptance score	0.146	0.089
Change in athletic competence score	0.085	0.217
Change in physical appearance score	0.144	0.091
Change in global self-worth score	0.283	0.004

6.4.4.2 Children's and parents' physical activity measures

Hypotheses 7, 8 and 9 concerned the self-reported physical activity measures. Tables 6.12 and 6.13 display the results of the children's and parents' physical activity measures from pre-intervention assessment to post-intervention assessment.

Table 6.12 Change in children's physical activity measures from pre-intervention assessment (0 months) to post-intervention assessment (3 months)

	0 months Mean (SD) (n=87)	3 months Mean (SD) (n=87)	0-3 month change (n=87)	
			Mean (95% CI)	*p* value
How important is physical activity to you? 0 = Not important at all, 10 = Extremely important	7.44(2.40)	8.34(2.10)	0.91 (0.39 to 1.43)	0.001
How many days a week (on average) do you spend doing the following? Total of 60 minutes on physical activity – at a 'moderate pace'	4.07(1.88)	5.30(1.54)	1.23 (0.78 to 1.68)	<0.0005
How many days a week (on average) do you spend doing the following? Total of 40 minutes on an activity that makes you sweat or out of breath	3.22(1.95)	4.40(1.85)	1.18 (0.67 to 1.68)	<0.0005

Table 6.13 Change in parents physical activity levels from pre-intervention assessment (0 months) to post-intervention assessment (3 months)

	0 months Mean (SD) (n=75)	3 months Mean (SD) (n=75)	0-3 month change (n=75)	
			Mean (95% CI)	*p* value
How important is physical activity to you? 0 = Not important at all, 10 = Extremely important	6.68(2.41)	7.79(1.88)	1.11 (0.79 to 1.77)	<0.0005
How many days a week (on average) do you spend doing the following? Total of 30 minutes on physical activity – at a 'moderate pace'	3.25(2.14)	4.53(1.77)	1.28 (0.80 to 1.79)	<0.0005
How many days a week (on average) do you spend doing the following? Total of 20 minutes on an activity that makes you sweat or out of breath	2.21(2.24)	3.51(1.95)	1.30 (0.66 to 1.56)	<0.0005

Children significantly increased their score of how important physical activity was to them when measured on a scale of 1 – 10, with 1 being not important at all and 10 being extremely important, from 7.44 to 8.34 ($p = 0.001$). Children also significantly increased the number of days a week they completed 60 minutes of physical activity (1.23, 95% CI: 0.78 to 1.68, $p < 0.0005$, n=87), and significantly increased the number of days a week they took part in activity at an increased intensity (1.18, 95% CI: 0.67 to 1.68, $p < 0.0005$, n=87) (table 6.12). At pre-intervention assessment 10 children reported meeting the

CMO's minimum recommendation of 60 minutes activity every day. At the post-intervention assessment 25 children reported they met the recommendation.

Results from the questionnaire showed parents also significantly increased their score of how important physical activity was to them, 6.68 to 7.79 ($p < 0.0005$). Parents also reported a significant increase in the number of days a week they completed 30 minutes of physical activity at a moderate pace (1.28, 95% CI: 0.80 to 1.79, $p < 0.0005$), and significantly increased the number of days a week they took part in activity for 20 minutes at an increased intensity (1.30, 95% CI: 0.66 to 1.56, $p < 0.0005$) (table 6.13). The number of parents meeting the CMO's recommended activity level of 30 minutes on five days of the week increased from 5 at pre-intervention assessment to 17 at the post-intervention assessment.

Analysis for hypothesis 10 (overweight and obese parents who increase their activity levels the most will have the greatest effect on their own BMI), and hypothesis 11 (parents who make the most improvements in their activity levels will have children who report the greatest improvements in activity levels also), both showed no significant correlation.

6.4.4.3 Children's fruit and vegetable consumption

Average daily fruit and vegetable consumption was gathered from the 3 day food diary as described in section 6.3.8.4 and analysed to address hypotheses 12 and 13. According to the 3 day food diary completed by the children fruit and vegetable consumption significantly increased from pre- to post-assessment (1.23, 95% CI: 1.05 to 1.41, $p < 0.0005$) (table 6.14).

Table 6.14 Change in children's fruit and vegetable consumption from pre-intervention assessment (0 months) to post-intervention assessment (3 months)

	0 months Mean (SD) (n=59)*	3 months Mean (SD) (n=59)*	0-3 month change (n=59)*	
			Mean (95% CI)	*p* value
Fruit and veg consumption (portions/day)	1.75(0.89)	2.98(0.96)	1.23 (1.05 to 1.41)	<0.0005

* n is less due to not all children returning their diary and incomplete diaries

Analysis of the food diaries showed no children reported eating the recommended 5 portions of fruit and vegetables at pre-assessment, and two children achieved this at post-assessment. Examination of the food diaries using '4 a day' showed two children achieved this at pre-assessment and 13 children ate 4 portions of fruit and vegetables a day at post-assessment. Overall, 56 children increased the number of portions of fruit and vegetables they ate from pre- to post-assessment, with 1 child reporting the same and three children decreasing the amount of fruit and vegetables they ate.

6.4.5 Results of planned analysis against hypotheses

Results of the planned analysis are shown in table 6.15. Some of the data has been presented in previous sections. This section describes the hypotheses showing some correlation or significance.

Table 6.15 Results of planned analyses for the feasibility study

Number	Hypotheses	Outcomes	Results
Primary outcome			
1	Children who complete the programme will decrease their BMI z-score at 12 weeks	BMI *z*-score	There was a significant reduction from pre-assessment by -0.12 (95% CI: -0.14 to -0.09, $p < 0.0005$, n=87)
2	Overweight and obese parents who complete the programme will decrease their BMI		Overweight and obese parents significantly reduced their BMI at post-assessment by -0.50 kg/m^2 (95% CI: -0.29 to -0.71, $p < 0.0005$, n=65)
3	Overweight and obese parents who make the most improvement in their BMI will have children who achieve the greatest improvement in their BMI z-score		There was a small positive correlation (r=0.251, $p < 0.05$, n=65) with improvement in parental BMI associated with improvements in child BMI z-score
4	Children and parents who complete the programme will maintain their improvements in their BMI over the 9 month post-baseline period		Children maintained their improvements at 6 months (-0.15, 95% CI: -0.20 to -0.11, $p < 0.0005$, n=87). Parents improved their BMI at 6 months (-0.85, 95% CI: -1.28 to -0.42, $p < 0.0005$, n=74)
Secondary outcomes			
5	Children who complete the programme will increase their self-esteem	Self-esteem	Children's self-esteem change significantly for all of the 4 domains measured; Social acceptance (0.32, 95% CI: 0.21 to 0.44, $p < 0.0005$, n=87) Athletic competence (0.37, 95% CI: 0.27 to 0.46, $p < 0.0005$, n=87) Physical appearance (0.29, 95% CI: 0.19 to 0.40, $p < 0.0005$, n=87) Global self-worth (0.31, 95% CI: 0.21 to 0.41, $p < 0.0005$, n=87)

Table 6.15 (Cont'd) Results of planned analyses for the feasibility study

Number	Hypotheses	Outcomes	Results
6	Children who report the greatest increase in self-esteem will show the greatest improvements in their BMI z-score		There was a small positive correlation (r=0.24, $p < 0.05$, n=87) with increases in self-esteem associated with improvements in BMI z-score
7	Children who complete the programme will increase their physical activity levels	Self-reported physical activity	Children significantly increased their physical activity levels; Number of days a week they completed 60 minutes of physical activity (1.23, 95% CI: 0.78 to 1.68, $p < 0.0005$, n=87) Number of days a week they took part in activity at an increased intensity (1.18, 95% CI: 0.67 to 1.68, $p < 0.0005$, n=87)
8	Children who increase their activity levels the most will have the greatest improvements in BMI z-score		No significant correlation
9	Children who improve how important physical activity is to them the most will have the greatest improvements in BMI z-score		There was a small positive correlation (r=0.242, $p < 0.05$, n=87) with improvements in how important physical activity is to them associated with improvements in BMI z-score
10	Overweight and obese parents who increase their activity levels the most will have the greatest effect on their own BMI		No significant correlation
11	Parents who make the most improvements in their activity levels will have children who report the greatest improvements in activity levels also		No significant correlation
12	Children who complete the programme will improve their fruit and vegetable consumption	Self-reported fruit and vegetable consumption	Fruit and vegetable consumption significantly increased (1.23, 95% CI: 1.05 to 1.41, $p < 0.0005$, n=59)
13	Children who increase the amount of fruit and vegetables they consume the most will have the greatest beneficial effect on their BMI z-score		No significant correlation

Table 6.15 (Cont'd) Results of planned analyses for the feasibility study

Number	Hypotheses	Outcomes	Results
Process evaluation measure			
14	Families completing the programme will improve their reported healthy family behaviours	Healthy family behaviours	Reported family behaviours improved significantly for all themes; Food and drink (1.38, 95% CI: 1.14 to 1.62, $p < 0.0005$, n=87) Exercise (1.27, 95% CI: 1.15 to 1.38, $p < 0.0005$, n=87) Family behaviour, (1.04, 95% CI: 0.94 to 1.14, $p < 0.0005$, n=87) Positive parenting (1.06, 95% CI: 0.94 to 1.18, $p < 0.0005$, n=87)
15	Parents reporting the greatest changes in healthy family behaviours will have the most beneficial effect on their child's BMI z-score		There was a small positive correlation (r=0.206, $p < 0.05$, n=87) associated with increases in the Family Behaviour theme with improvements in BMI z-score. No other correlations were significant
16	Overweight and obese parents reporting the greatest changes in healthy family behaviours will have the greatest improvements in their own BMI		No significant correlation

There was a small positive correlation (r=0.251, $p < 0.05$, n=65) between overweight and obese parents who made the most improvement in their BMI and improvement in their children's BMI z-score, with improvement in parental BMI associated with improvements in child BMI z-score (hypothesis 3).

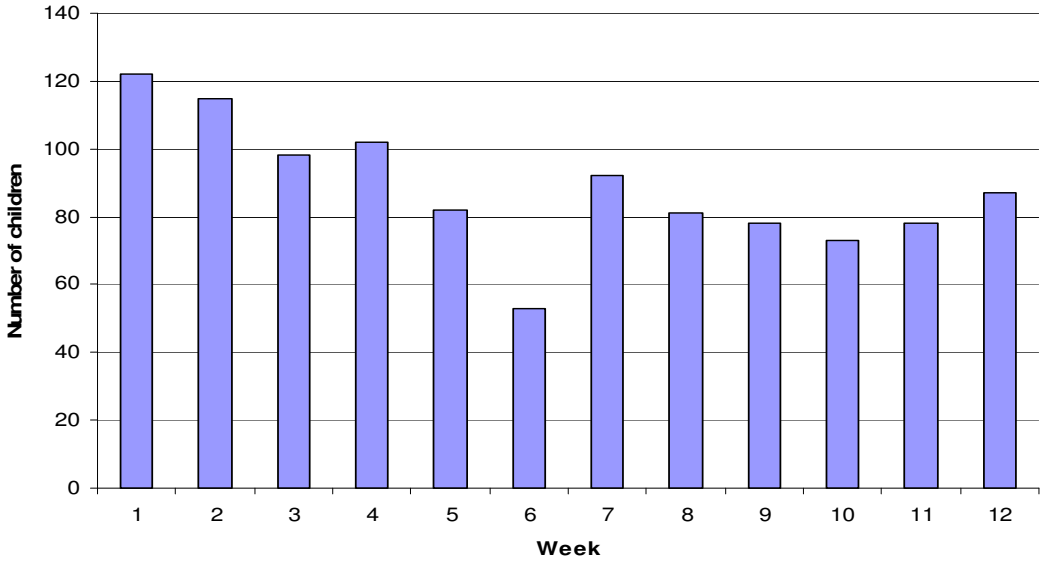
Children who reported the most improvement in the importance of physical activity to themselves showed a small positive correlation (r=0.242, $p < 0.05$, n=87) with improvements in their BMI z-score, with improvements in the importance of physical activity being associated with improvements in BMI z-score (hypothesis 9).

6.4.6 Process evaluation measures

6.4.6.1 Register of attendance

A register of attendance was kept for each week of the programme for all groups. Figure 6.4 shows the weekly attendance at Y W8? for all groups. Figure 6.5 displays the percentage attendance against the total still in the programme at that week.

Figure 6.4 Children's weekly attendance at Y W8? for all groups



The figure shows children's attendance at the group gradually decreased as the programme progressed. Attendance at week 6 was low as it was the half-term session and some families were away on holiday. This also accounts for a small number of families who could not attend week 5 due to the half-term break. Information regarding reasons why families did not start the programme or did not complete the programme is given in section 6.4.6.4.4.

Figure 6.5 Percentage of children attending against total still in the programme that week

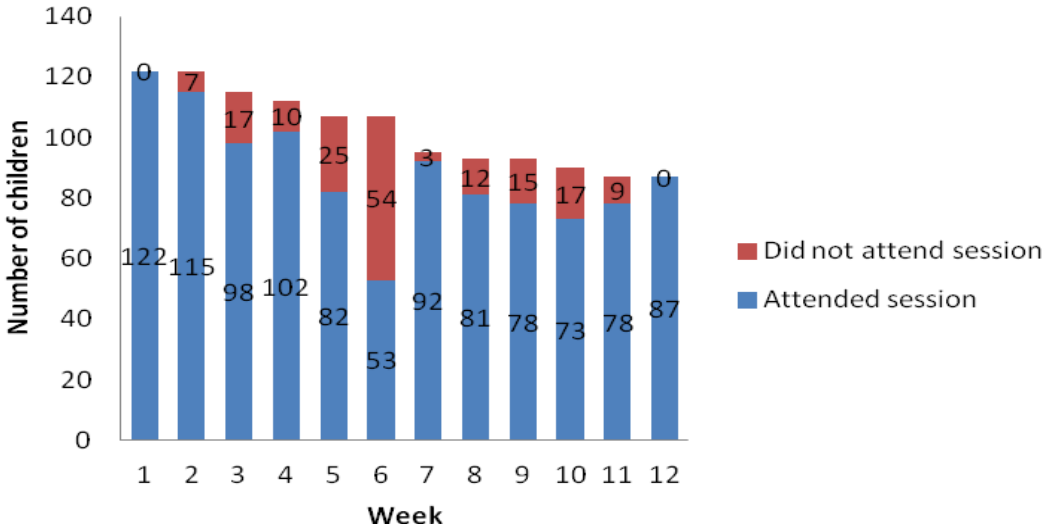


Figure 6.5 shows how the attendance at weekly sessions gradually decreased as the programme progressed. The figure shows a particular drop out between weeks 6 and 7. This was noted across most groups and seemed to be due to the half-term break causing a change of routine for families which then led to them finding it difficult to re-engage with the programme. Ninety-two percent of families who remain engaged after half-term, (attended week 7), completed the programme.

6.4.6.2 Programme fidelity measures

6.4.6.2.1 Healthy Family Behaviours Questionnaire

The Healthy Family Behaviours questionnaire was completed by the parents and used to analyse hypothesis 14. Parents bringing more than one child were asked to complete the

questionnaire for each child. The 25 statements included in the questionnaire were grouped into themes; food and drink, exercise, family behaviour and positive parenting. Parents reported a significant improvement in behaviours across all themes ($p < 0.0005$). The results are shown in table 6.16.

Table 6.16 Healthy Family Behaviours Questionnaire results

	0 months Mean (SD) (n=87)	3 months Mean (SD) (n=87)	0-3 month change (n=87)	
			Mean (95% CI)	*p* value
Food and drink	6.94(1.26)	8.32(0.96)	1.38 (1.14 to 1.62)	<0.0005
Exercise	2.45(0.55)	3.71(0.48)	1.27 (1.15 to 1.38)	<0.0005
Family behaviours	2.81(0.49)	3.85(0.56)	1.04 (0.94 to 1.14)	<0.0005
Positive parenting	2.73(0.51)	3.79(0.51)	1.06 (0.94 to 1.18)	<0.0005

Table 6.17 displays these results as actual number, and percentage, of parents who made improvements, stayed the same and deteriorated in the self-reported behaviours. The results show 91% of parents reported improvements in Food and drink themed behaviours such as 'My child drinks fizzy pop at home' and 'My child eats breakfast everyday'. Regarding the Exercise theme, 89% of parents felt they had made improvements in behaviours such as 'I encourage my child to exercise' and 'My child watches more than 2 hours of television during the day'. The Family behaviours theme displayed the lowest number of parents reporting improvements compared with the other themes, at 69%. Statements included in this theme included; 'We eat in front of the TV' and 'We eat meals together as a family'. Finally, results show 78% of parents reported improvements in Positive parenting themed behaviours such as 'As a parent I use food to reward good behaviour' and 'I set a good example by eating a healthy diet'. Further details regarding the questionnaire can be found in appendix 27.

Table 6.17 Healthy Family Behaviours Questionnaire results – actual number of parents making changes (n=87)

	Increased score for behaviours	Stayed the same	Decreased score for behaviours
Food and drink	79 (91%)	3 (3%)	5 (6%)
Exercise	77 (89%)	5 (5.5%)	5 (5.5%)
Family behaviours	60 (69%)	17 (20%)	10 (11%)
Positive parenting	68 (78%)	7 (8%)	12 (14%)

Parents reporting the greatest changes in the Family behaviours theme of the Healthy Family Behaviours Questionnaire had the most beneficial effect on their child's BMI z-score with a small positive correlation ($r=0.206$, $p < 0.05$, $n=87$) being associated with improvements in BMI z-score (hypothesis 15). Analysis addressing hypothesis 16 showed no correlation between overweight and obese parents reporting the greatest changes in healthy family behaviours and changes in their own BMI.

6.4.6.2.2 Y W8? mentor session content evaluation (fidelity) sheet

The evaluation sheets were reviewed weekly to ensure fidelity to the programme content. Slight adjustments were made to the timings of week 4 and week 8 parent and child workshops, and week 3 and week 11 parent workshops to ensure all the content could be covered in the sessions.

6.4.6.3 Graffiti wall

The graffiti wall was a productive way of getting feedback from both children and parents. The children, in particular, found it a stimulating activity and were keen to be able to put something on the wall. The parents seemed to view it as a children's activity at the start and had to be encouraged to give their feedback in this manner. An example graffiti wall is shown in figure 6.6.

Figure 6.6 Example graffiti wall

6.4.6.4 Post-programme evaluation by parents and children

6.4.6.4.1 Analysis of interviews with parents

Table 6.18 shows the family details of the parents who were interviewed and table 6.19 shows illustrative quotes concerning the outcome evaluation measures focused on in the programme and their views of the intervention content and delivery.

Table 6.18 Family details of parents who were interviewed

	Gender	Child details		
		Number of children	Child gender	Child age
1	Female	2	Female Male	11 13
2	Female	1	Female	11
3	Female	1	Female	9
4	Female	1	Female	13
5	Female	1	Male	8
6	Female	1	Female	10

The interviews with the parents were also used as an opportunity to gain an in-depth understanding of their opinions of each aspect of the programme and any concerns they had. Table 6.20 shows a selection of their comments.

Table 6.19 Illustrative quotes concerning the outcome evaluation measures focused on in the programme

Outcome evaluation measure	Illustrative quotes
Change in child's BMI	• *"I feel relieved that she is now able to get clothes nearer her age cause before, you know, it was much, much, sort of bigger, cause certain clothing well we always had to make sure it had elasticated waists and now we don't which makes her feel far more confident and as a result I feel much happier for her"* (Mother 3) • *"Her clothes fit her better and she's definitely got taller. The clothes I'm getting her are the same size as last year, but I'm not having to turn them up"* (Mother 4) • *"Yes we've definitely noticed a difference and his aunty saw him the other day, and she hadn't seen him for a couple of months, and she told me how much slimmer he looked you know, not thin obviously, just less tubby"* (Mother 5)
Change in parent's BMI	• *"I have improved. I used to just make sure the kids were alright and then just grab whatever, but I have got better and I've joined Why Weight Plus, so I've joined that and I'm really enjoying that. I've just joined a gym as well which I thought I'd never do and I love it, so it's really helped me get the confidence to do that kind of thing"* (Mother 1) • *"I haven't made changes no not really. I think I've just been on yo-yo diets for so many years, um, again I know the stuff, I know what I should be doing. It has helped me and I am more conscious definitely for the children. I have cut down on buying crisps and biscuits and things for the family but I like to have my own things, you know, when they're in bed"* (Mother 4)
Change in child's self-esteem level	• *"She's definitely more confident than she was and I think that's all related to how she feels about herself"* (Mother 6) • *"She's definitely more confident because, well with after school clubs there are certain ones she would want to be involved with, sort of craft based or sort of like maths based like chess, or something like that, but she wouldn't have been interested in anything sort of physical because I suppose as much as anything else she wasn't confident about her own ability in taking part and now as a result of being more confident in how she looks and feels she is prepared to take part and just thinks well it's a game, it's fun"* (Mother 3)

Table 6.19 (Cont'd) Illustrative quotes concerning the outcome evaluation measures focused on in the programme

Outcome evaluation measure	Illustrative quotes
Change in child's physical activity levels	• *"[Child's name] is definitely healthier. She's much more active, which we thought she was anyway, but it's more constructive active now, if you know what I mean, so she's doing more, she's given up gymnastics, cause of her leg, but she's doing lots more fun exercises and wanting to go for walks more and wanting to go out more, so she not just sitting in front of the telly"* (Mother 2) • *"His exercise has improved too. There are lots of clubs after school, but he didn't actually go to any of them but now he's happy to join in, and he's made new friends. He's done the bikeability thing at school which he wouldn't have wanted to do before, and little changes like that which all add up, and now he thinks things are fun which is different to before"* (Mother 5)
Change in parent's physical activity levels	• *"Well I knew exercise was important, obviously, but I must admit because I don't really enjoy it I hadn't really bothered too much with her but the week where we talked about exercise, you know, the benefits and that, well I thought my dad died of a heart attack and I don't want that happening to me so I am trying. We've started to walk to school and, well that's good"* (Mother 6) *"I am trying you know. The free sessions you offer are great and I join in them when I can, cause the kids always bug me if I don't, and I do like it when I'm doing it, doing all these things is expensive for us"* (Mother 1)
Change in child's fruit and vegetable consumption	• *"They are more conscious now. They say, 'oh I need more pieces of fruit today' and we keep the plate on the fridge constantly so it helps me remember"* (Mother 1) • *"I've got better at offering them fruit. I make sure there is a piece in his lunchbox and the fruit bowl always has something in it now. I've noticed him and his brother will go and help themselves, which is great cause I don't have to nag or anything"* (Mother 5)
Healthy family behaviours – Food and drink	• *"I have changed yes. It's hard for people like myself that are busy, you know, I used to just throw anything on a plate. You don't think about what you're giving them. It was just like, ah, pizza will do tonight, or chippy on the way home. Now I try and plan and make sure I have shopping in so I can make something healthier"* (Mother 1) • *"I always used food as treats. I didn't realise how much I did, constantly used food as a reward, cause we were brought up like that, dad used to come home from work with a few sweets in his pocket for us, so that's been hard but I am trying"* (Mother 2) • *"Portion control I found really quite shocking really. We were having too big a portions and I've really tried to think about what goes on the plate you know. It's tricky but I'm trying"* (Mother 3)

Table 6.19 (Cont'd) Illustrative quotes concerning the outcome evaluation measures focused on in the programme

Outcome evaluation measure	Illustrative quotes
Healthy family behaviours – Exercise	• *"I'm definitely encouraging her to do more, yes definitely. Encouraging her to go out in the garden, play out on her trampoline and that. I still struggle though, just don't have time really, and I suppose, well, I'm so unfit I don't know where to start"* (Mother 3) • *"The children do more. I make a real effort to, you know, get them out in the garden. Well its summer at the moment so it's easier, and I enjoy being out there with them. It will be more difficult later, you know, when the weather isn't good and it gets dark"* (Mother 1)
Healthy family behaviours – Family behaviours	• *"It's hard doing it as a family, because my son will come in and stuff himself with biscuits and she'll say, well I want to do that and I, you know, just have to, so now we just don't do the biscuits, we don't have the biscuits very often, so then it's just not an issue"* (Mother 2) • *"I remember the bit about sitting down together to eat. I make a point of doing it at the weekends, it's too difficult during the week, too hectic you know, but it's nice, the kids thought it was a pain at first but I've stuck to it"* (Mother 6) • *"I only let her have an hour of telly a day. She went to her friends once and watched it there, she came back and said 'oh I've watched it for 5 hours today' and she felt guilty about it, so she's learnt that, you know, it's not doing her any good"* (Mother 4)
Healthy family behaviours – Positive parenting	• *"The role model stuff was like wow, I didn't realise how much they looked up to us, until we did it, that was a bit of a shock, cause my partners not really into this at all so that's really hard, cause it's us 3 against him and they're always nagging him but it does make things tough, but you can't change the world"* (Mother 1) • *"The challenge charts you gave us, he loved it, loved it. Yeah he absolutely thought that was brilliant, and it was competition cause his brother joined in and there was the 3 of us doing it, cause they made me stick my name on it too, and I always lost but the kids, well it was such a challenge for them and they did really well when we used the chart"* (Mother 5) • *"I try and use the goal setting and rewards. The children really like that. I let them pick their own goal for the week"* (Mother 2) • *"Monitoring was useful. You really see what you do. I didn't realise what I ate. So when we sat down and wrote the diary you're shocked at what you're eating that day you know"* (Mother 4)

Table 6.20 Illustrative quotes showing parents opinions of each aspect of the programme and their concerns

Aspect of the programme	Illustrative quotes
Child and parent workshops	• *"I like the supermarket week. A great idea. Actually showing you what's good in the shop and what's not and reading the packaging properly"* (Mother 6) • *"Being able to spoon out the amount of sugar in food like sweets and that, well, it makes you focus on what's in food, and it's certainly helped us to think about what we eat, what she's putting into her body, how much exercise she's doing"* (Mother 2) • *"Log foods is something that sticks in my mind, and when you drew that graph of their blood sugars, I remember that. We changed to wholemeal bread cause of that and stopped so much of the junky stuff you know"* (Mother 4)
Parent workshops	• *"It was good because we could talk about all the issues we had. We weren't lectured at, we could just bring up all our issues, like one doesn't eat healthy things, the other eats too much and is an emotional eater, and with one of each it's hard to know what to do and they were really good at helping us with ways around that, giving us ideas"* (Mother 1) • *"Being able to talk to all the other parents was helpful. We learnt something each week as well, each week we went there was a new focus, but it was actually just talking to the other parents, finding out you weren't alone in this, that was, I think, the most, you know, having an open forum to say my kid does that too, cause you feel so guilty and it's not about guilt it's about learning"* (Mother 5)
Children's activity sessions	• *"She was wowed when she came back from the activity session. She loved it. It was great to see her smiley face when she got back. She liked going in the gym. Being able to work out on the equipment made her feel grown-up, she thought that was fantastic. Yeah, she felt really grown-up and she was in college too so that was exciting for her"* (Mother 6) • *"The team games were good. Boost their confidence to join in with their mates. Cause some of these kids are really isolated so they need team sports to encourage them to join in"* (Mother 3)

Table 6.20 (Cont'd) Illustrative quotes showing parents opinions of each aspect of the programme and their concerns

Aspect of the programme	Illustrative quotes
Half-term family activity	• *"It was good and getting the parents to join in was brilliant cause, you know, I would never do any exercise but it was done in a different way and it was just fine really. The kids wanted the parents to join in, you know, they really wanted you to do it, and a few parents did stand by because they weren't comfortable doing it but you could see the kids really want their parents to join in, and we tried things, and it was funny cause we weren't very good but it was fun having a go"* (Mother 3) • *"The more events like that families can go to the more confident the parents would get and the children get so much out of it, and everyone really enjoys it, you know with their parents as well cause sometimes that's the only time they've got with their parents, which is a sad thing, but a lot of kids don't get a lot of time with their parents"* (Mother 4)
Y W8? 2 Get Cooking sessions	• *"The cooking was brilliant. We all loved that. I can't cook to save my life so that was really good and the kids loved it cause they got to do most of it. It has improved my confidence. I do try things that aren't just in packages now, and my kids, yes, I realise that at the age they are they can help now, you know they're old enough so I'm getting a bit better and the kids love it"* (Mother 1) • *"You really got to see what went in the food, it wasn't the expensive things. I thought everything would be really expensive and it would be the best foods in the supermarkets and it wasn't , it was just basic food and you just throw it all together and it was lovely"* (Mother 5)
Y W8? Activ8! Sessions	• *"The free session for exercise is great, we really enjoy it, and cause I can take her brother as well, that's a real bonus, I couldn't afford for both of them to go to the gym, well it's expensive isn't it?"* (Mother 6) • *"She was disappointed we couldn't get to the sessions but X [child's brother] has football training at the same time, and, well, that's just a timing issue for us, we can't do it all, and he loves his football, so, yeah, we couldn't make it"* (Mother 2)
Y W8? Free gifts	• *"The bag was really good but with the logo on, well they don't want to use it at school cause they have to explain what it means. It was useful for taking things to the sessions but you know she said, it's got the logo on it and daughter's only 10 and she's quite childish and she's happy to go along with things but she was worried that the kids might make fun of her"* (Mother 6) • *"Water bottles were great, really useful"* (Mother 4) • *"The pedometers weren't great cause they can just shake them, you know sitting in front of the telly shaking it, well cheating"* (Mother 3)

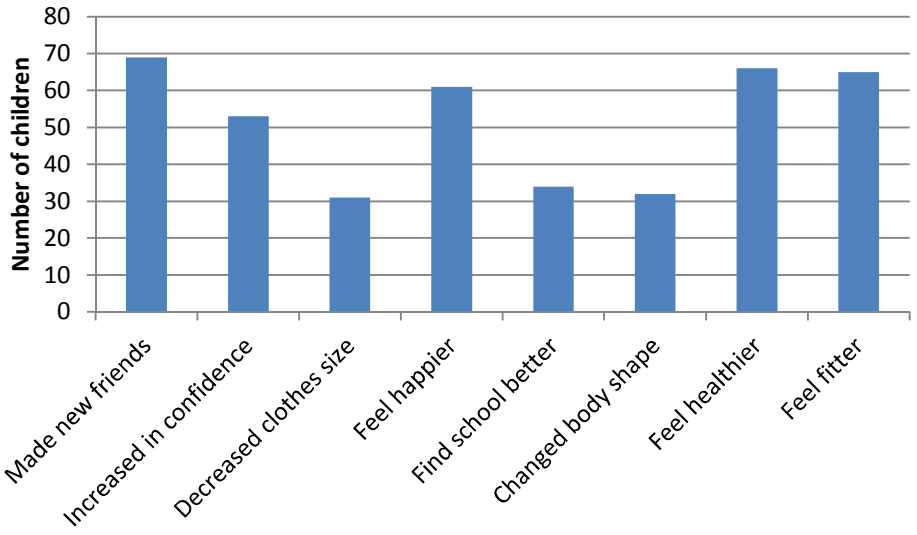
Table 6.20 (Cont'd) Illustrative quotes showing parents opinions of each aspect of the programme and their concerns

Aspect of the programme	Illustrative quotes
Y W8? Folders	• *"The folders were great because [child's name] has got hers still and she's got all her notes in it so it's definitely worthwhile, and the parents have one so that's a good reference guide"* (Mother 2) • *"Very useful to have the folders and things, cause we can refer to them now. It's very easy to forget all the different things, you know, sometimes you just need to refresh your memory"* (Mother 4)
Concerns	• *"It was great during the 12 weeks on the Fridays doing the exercise and everything, and she does trampolining and skating, which are active, but not a really good work out like at Y W8? It's not an hour of getting her fitter. I am concerned that what she's done over the 12 weeks is going to lapse very quickly"* (Mother 2) • *"It's difficult to get all the things in one week. What with my other children as well, coming on a Friday night we managed, but it's difficult you know"* (Mother 6) • *"Well we will use the challenge chart again, you know, we missed a few weeks and sort of lost track of the chart you know, but we could get some more stickers and do it all together, cause I think that's what you need sometimes isn't it? Something to follow"* (Mother 5) • *"We became less enthusiastic at the end. It was when we went to ASDA and, I don't know, after that week, I don't know, we just went a bit off track then"* (Mother 2) • *"Since it's stopped, you know, we've stopped going, we've lost eating more healthier. I don't know why, and she's stopped exercising as much you know. We've lost motivation for it all"* (Mother 6)

6.4.6.4.2 Evaluation of user views by children

All children who completed the programme completed a Y W8? children's user evaluation (appendix 30). The results are reported in this section. Figure 6.7 displays the results for the question; 'Since attending Y W8? have you ……..?' Children were prompted to tick as many as were applicable.

Figure 6.7 Results of the question; 'Since attending Y W8? have you .....?'



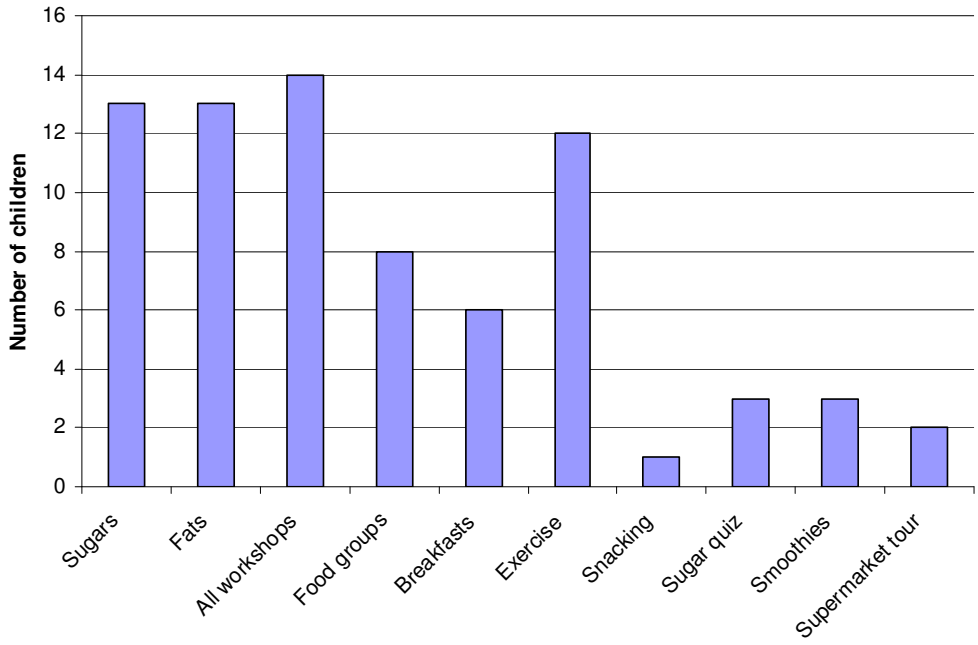
(n=87)

The responses selected the most were; Made new friends (n=69), Feel healthier (n=66), Feel fitter (n=65) and Feel happier (n=61). No children ticked all of the options.

The Y W8? children's user evaluation asked respondents about the parent and child workshops they attended. Most children rated the workshops very good (n=60, 69%) or good (n=22, 25%). Six percent (n=5) thought the workshops were fair and no children rated the workshops poor. Eighty-three percent thought the workshops were of the right length, with the rest of the responses being split equally between 'Too long' and 'Too short'. The children were also asked which workshops they found the most and least

useful. Children were asked to list all the workshops they found the most and least useful. The results for the workshops found the most useful are shown in figure 6.8.

Figure 6.8 Workshops children found the most useful

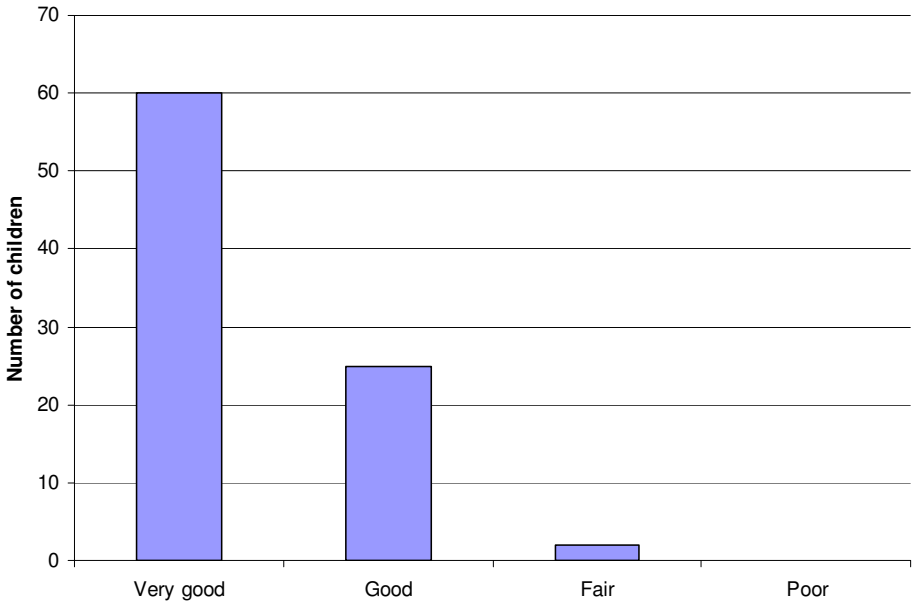


(n=87)

Many children found all the workshops useful. Workshops on sugars, fats and exercise were also rated highly. Few responses were given for the workshops found the least useful, with the food plate, fats and salt having one response each.

The children's physical activity sessions were also highly rated (figure 6.9).

Figure 6.9 Ratings for the children's physical activity sessions

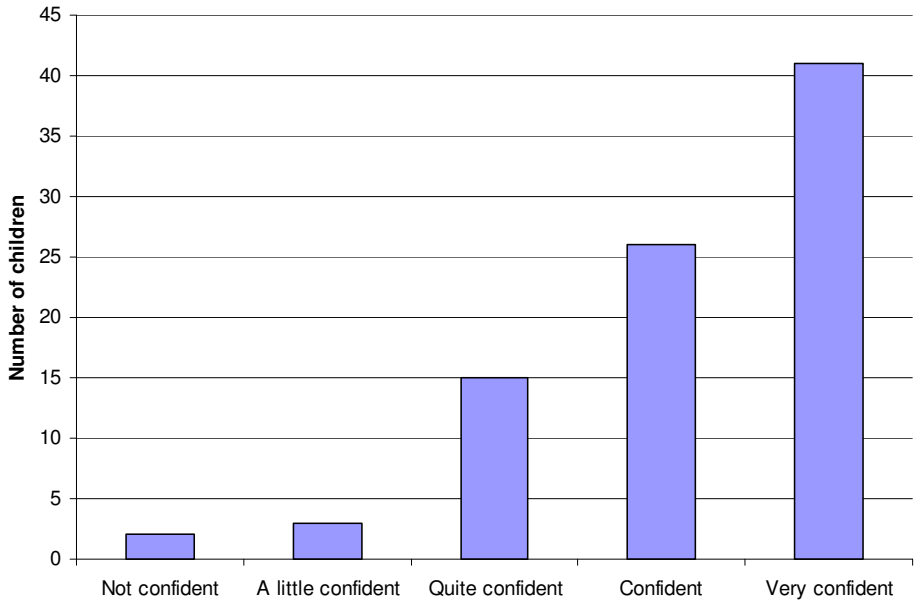


(n=87)

Figure 6.9 shows most responses were either 'Very good' (68%) or 'Good' (30%). Ninety-two percent of children reported the sessions had increased their confidence and ability to play sports and 83% agreed it had given them the confidence to try new activities.

Children were asked about their confidence in managing their weight in the future (figure 6.10).

Figure 6.10 Children's confidence in managing their weight in the future



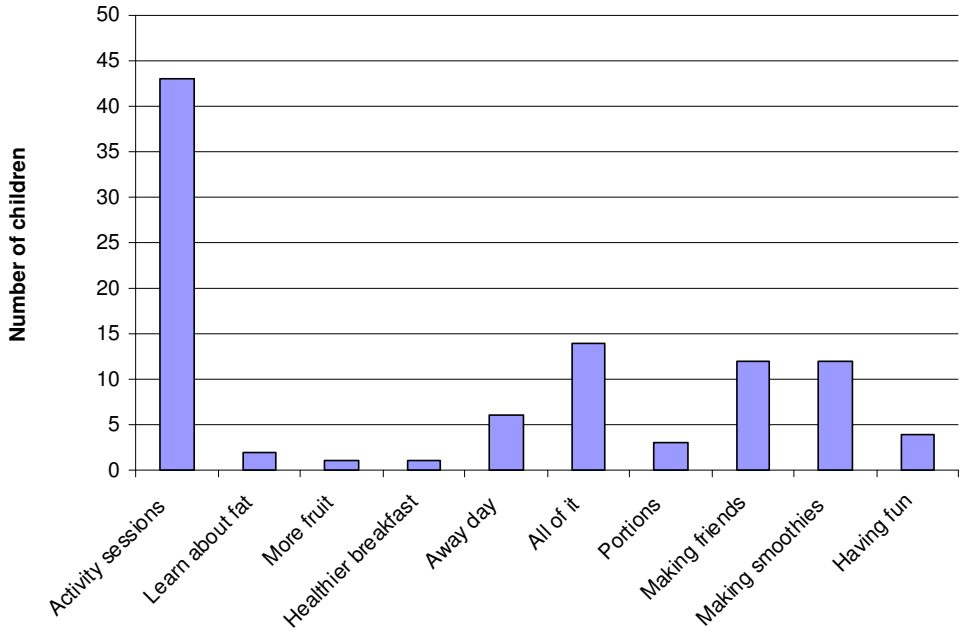
(n=87)

Forty-one percent of completers felt very confident and 24% confident in managing their weight in the future.

Completers feelings towards the 12 week length of the programme was also assessed with 70% of responders reporting the length was 'Just right' and 25% feeling it was 'Too short' and 5% responding it was 'Too long'.

The children were asked 'What were the best things about Y W8?', 'What were the worst things about Y W8?' and 'What other things could have been included to help you more?'. Children were able to list as many answers as were applicable. The results are shown in figure 6.11.

Figure 6.11 Children's responses to 'What were the best things about Y W8?'



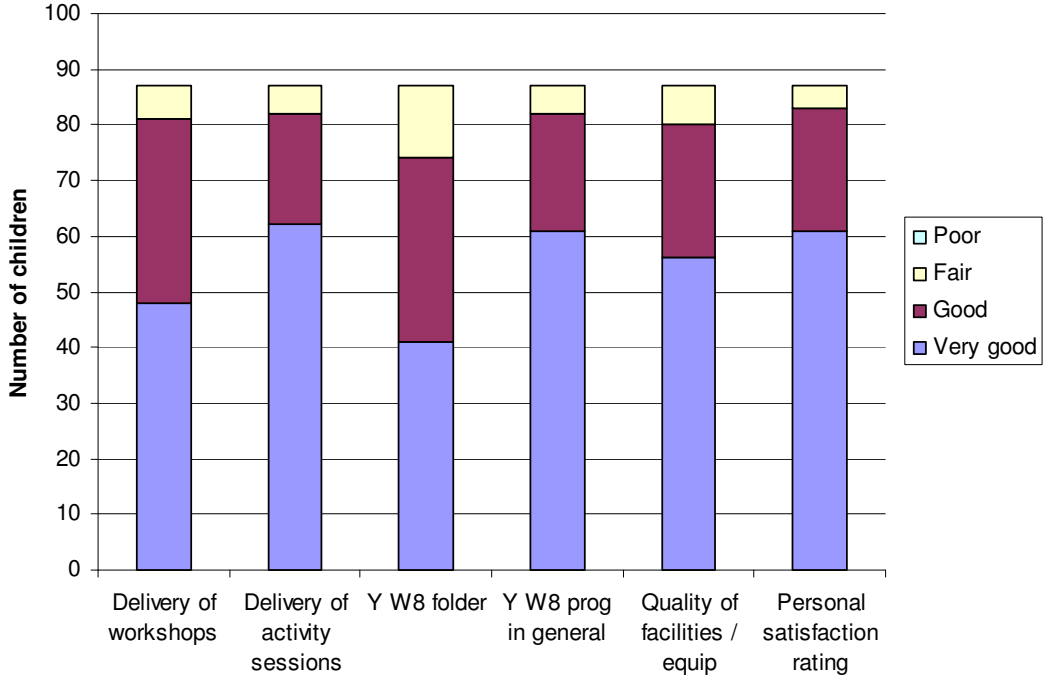
(n=87)

Figure 6.11 shows most children thought the activity sessions were the best thing, with 'All of it', 'Making friends' and 'Making smoothies' the most popular after this. There were few responses received for the 'Worst things about Y W8?' with 2 respondents disliking the group work, 2 not liking tasting seeds during the final group session, 1 completer finding it 'sometimes hard work' and 1 completer saying it was 'too long'.

There were also only a small number (n=8) responses to the question 'What other things could have been included to help you more?'. Three completers would have liked the programme to have been of a longer duration; 'More sessions' (n=2) and 'Gone on for longer' (n=1). Two children would have liked to have taken part in more sport, one child would have liked more activities with adults and children together, one child would have liked to have learnt about food from different countries and one child would have like to 'go to different places'.

Children were also asked to rate the programme and aspects of the programme using the scale; Very good, Good, Fair and Poor. Their responses are shown in figure 6.12.

Figure 6.12 Children's rating of the programme and aspects of the programme



(n=87)

The results showed most children rated the aspects of the programme as 'good' and 'very good'. No children rated any aspects of the programme as 'poor'.

Finally the children were asked about the changes they had made since attending Y W8? Children listed numerous changes they had made. These have been themed and example comments are shown in table 6.21.

Table 6.21 Children's changes made since attending Y W8?

Theme	Example comments
Increased physical activity levels	• *"Playing out more and playing more running game"* • *"More exercise and more confident doing sport"* • *"Doing more exercise"*
Decrease in sedentary behaviours	• *"Watching less TV"* • *"I don't watch as much TV and I don't play on my computer as much cause mum won't let me"*
Healthy eating	• *"Having wholemeal bread instead of white"* • *"Have more fruit and veg"* • *"Eat yellow peppers and drink more fluids"*
Breakfast	• *"Eating a healthy breakfast which I didn't do before"* • *"Eating breakfast before school"*
Changes to snacking	• *"Less chocolate and more fruit. Thinking more about what snacks to have"* • *"More fruit, less chocolate. Choosing healthier foods"* • *"Change to healthy snacks and no fizzy pop!"*
Decreased portion sizes	• *"Trying to cut down"* • *"Eating less and still staying full"* • *"Not pigging out as much"*
Self-esteem	• *"Being more confident"* • *"More confident doing sport and making decisions about my food"* • *"More confident at school"*
Trying new food	• *"Tried new food from cooking folder"* • *"Reading labels at the supermarket and trying new things"*
Change in body shape	• *"I go out with my friends more and I am thinner"* • *"Weight better and like shopping for clothes"* • *"Got a bit thinner"*
Cooking skills	• *"Learnt to cook"* • *"Make things from fresh"*
Sleep	• *"Have less sugar so sleep better"* • *"Don't stay up watch TV and go to bed earlier"*

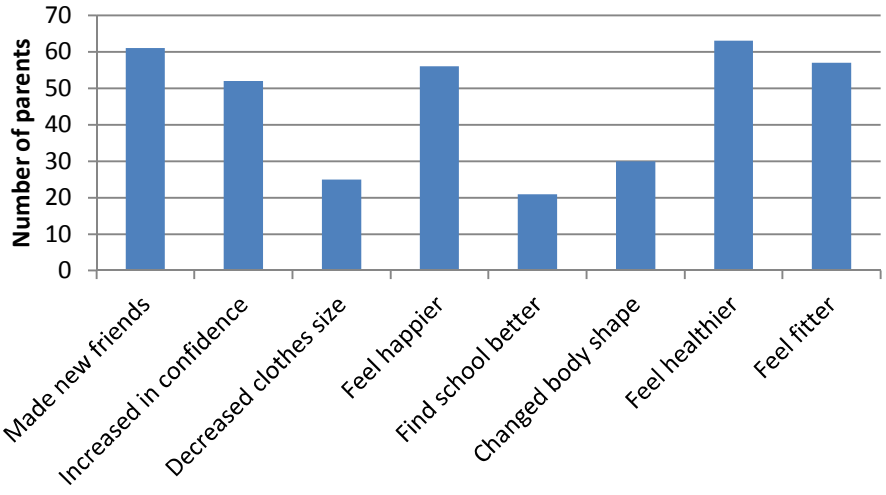
6.4.6.4.2.1 Summary of children's user evaluations

To summarise the children's evaluations, on the whole children who completed felt positive about the programme. Most made new friends, felt healthier, fitter and happier at the end. Children found the children and parent workshops useful, rated the physical activity sessions highly and most reported an increased confidence and ability to play sports. Since attending Y W8? 65% felt either confident or very confident in managing their weight in the future. A small number of children did not enjoy the group work and would have liked to take part in more sport.

6.4.6.4.3 Evaluation of user views by parents'

All parents who completed the programme (n=75) completed a Y W8? parent's user evaluation (appendix 31). The results are reported in this section. Figure 6.13 displays the results for the question; 'Since attending Y W8? do you feel that your child has ……..?' Parents were prompted to tick as many as were applicable.

Figure 6.13 Results of the question; 'Since attending Y W8? do you feel that your child has …..?

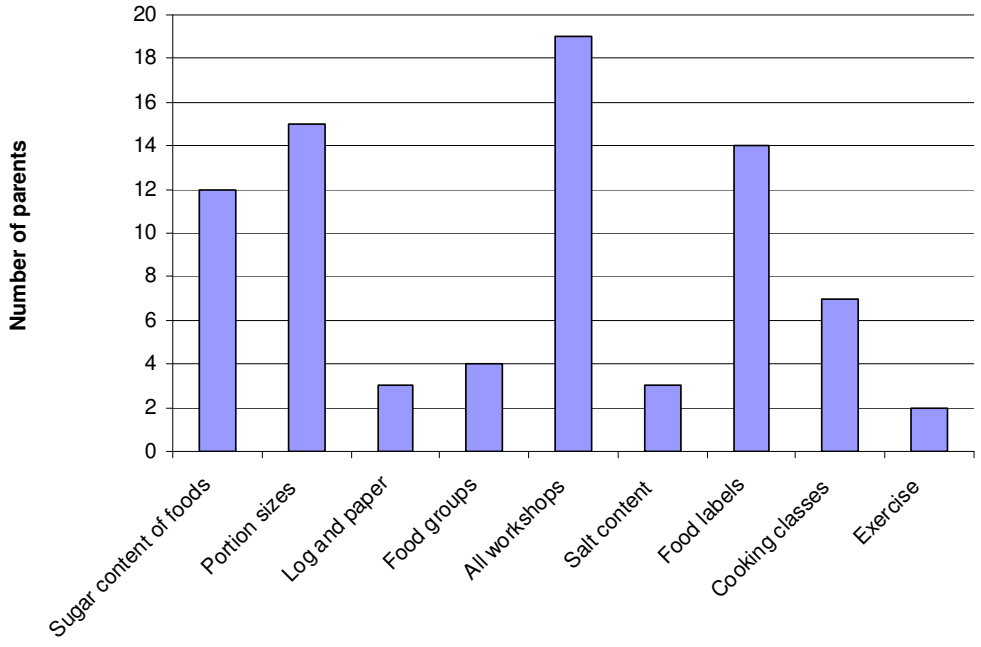


(n=75)

The responses selected the most were; Feel healthier (n=63), Made new friends (n=61), Feel fitter (n=57) and Feel happier (56).

The Y W8? parents' user evaluation asked respondents about the parent and child workshops they attended. Most parents rated the workshops very good (94%) or good (5%), with 1 parent rating the workshops as poor. Eighty-eight percent thought the parents only workshops were very good, 10% thought they were good and 2% rated them poor. The parents were also asked which workshops they found the most and least useful. The results for the workshops found the most useful are shown in figure 6.14.

Figure 6.14 Workshops parents found the most useful

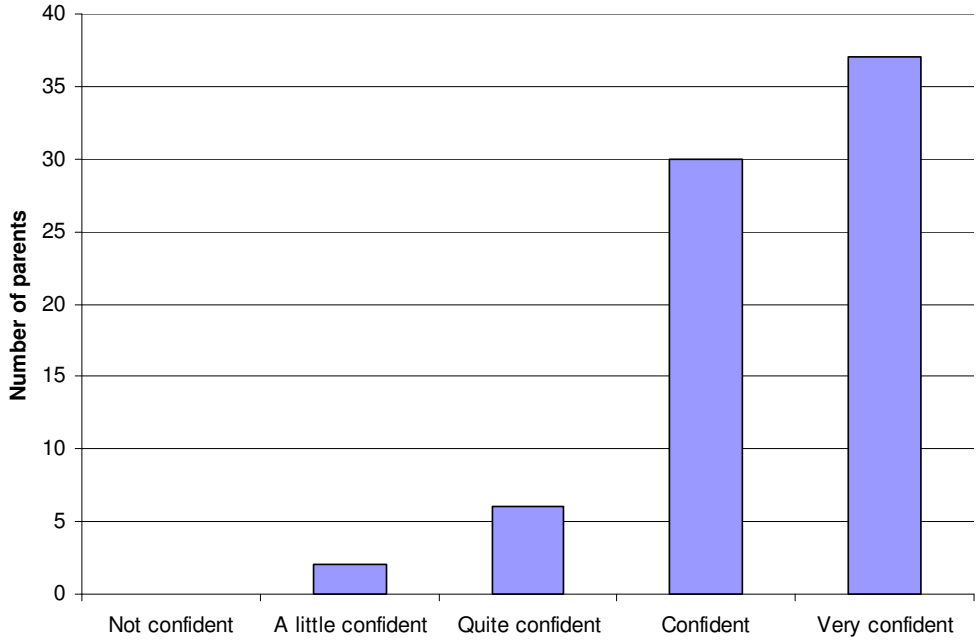


(n=75)

Many parents found all the workshops useful. Workshops on portion sizes, reading food labels and sugar content of foods were also rated highly. Few responses were given for the workshops found the least useful, with portion sizes and supermarket tour having one response each.

Parents were asked about their confidence in managing their child's weight in the future (figure 6.15).

Figure 6.15 Parents confidence in managing their child's weight in the future

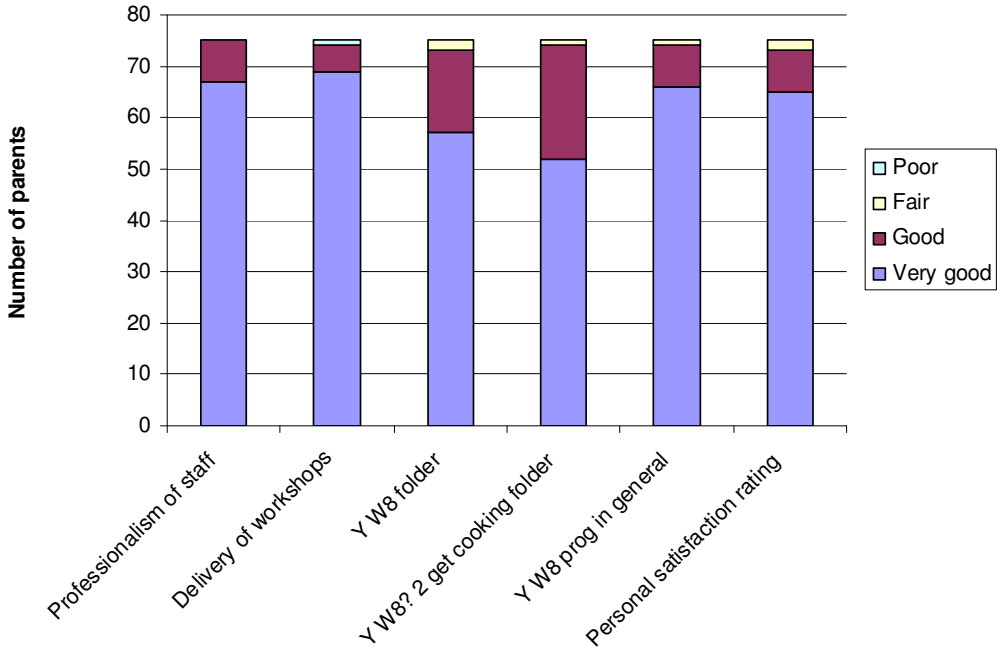


(n=75)

Fifty percent of parents felt very confident and 41% confident in managing their child's weight in the future. Ninety-three percent of parents reported that completion of Y W8? had enabled other members of the family to make positive changes to achieve a healthier lifestyle.

Parents were also asked to rate the programme and aspects of the programme using the scale; Very good, Good, Fair and Poor. Their responses are shown in figure 6.16.

Figure 6.16 Parents rating of the programme and aspects of the programme



(n=75)

The majority of parents rated all aspects of the programme ‘good’ or ‘very good’.

The parents were asked to list the changes their child had made since attending Y W8? Parents documented numerous changes. These have been themed and example comments are shown in table 6.22. Parents were also asked to list the changes that had been made for the rest of the family (table 6.23).

Table 6.22 Parents' comments of changes their child has made since attending Y W8?

Theme	Example comments
Increased physical activity levels	• *"More active"* • *"Now takes regular exercise"* • *"Plays out more and is enthusiastic about sport"*
Decrease in sedentary behaviours	• *"Reduced time spent on the computer"* • *"Spends less time watching TV and more time playing with friends"*
Healthy eating	• *"Eats porridge and wholemeal bread and asks for fruit as a snack"* • *"Less chocolate, crisps and chips – eats a more balanced diet"* • *"Less sugary foods and drinks"*
Breakfast	• *"Eats breakfast everyday without moaning!"* • *"Has improved what she has for breakfast"*
Changes to snacking	• *"Healthier snacks and drinking less tea with no sugar"* • *"No fizzy pops and eating less crisps"* • *"Drinks water not fizzy pop and has swapped fruit for crisps"*
Decreased portion sizes	• *"Cut out junk food and cut down on amount of food in general"* • *"Eating smaller portions"* • *"We are thinking about our portion sizes and having more veg on our plate instead"*
Self-esteem	• *"More confident – has found a love of boxing"* • *"Thinks for herself about healthy choices which has given her more confidence"* • *"He is happier and more out-going"*
Trying new food	• *"Try's new food without an argument and has a better understanding of why it's important to have a variety"* • *"He try's new food willingly"*
Sleep	• *"Going to bed earlier and sleeping well"* • *"Less sugar during the day so she seems to be able to settle down at night easier"*

Table 6.23 Parents' comments of changes made for the rest of the family

Theme	Example comments
Increased physical activity levels	• *"We all go out for walks"* • *"We have joined the gym to keep fit as a family"* • *"All the children are more active and we are aware of keeping active in the winter"*
Decrease in sedentary behaviours	• *"I turn the TV off and encourage them to go outside"* • *"They have to earn time on the computer by doing chores"*
Healthy eating	• *"I plan what to cook in advance and make sure the shopping is there"* • *"We have more fruit and veg and water"* • *"Avoiding high sugar and salt foods and generally a more balanced diet"*
Breakfast	• *"We all have breakfast"* • *"Having breakfast has been a big change for us"*
Changes to snacking	• *"Don't buy junk food and changed the snacks we have"* • *"Don't buy unhealthy snacks and have more fruit"* • *"I have taken control of the snacks"*
Decreased portion sizes	• *"Reduced portion sizes for everyone"* • *"Portion control at mealtimes"* • *"Smaller portion sizes"*
Cooking skills	• *I have changed my cooking techniques so they are healthier"* • *"Make things from fresh"* • *"We read food labels and decide what we want to cook"*
Healthy family behaviour	• *"We eat home cooked meals – this course has given me the kick to start cooking more at home"* • *"We don't have fast food anymore"* • *"We all sit at a table to eat"* • *"I plan the meals we are going to have and make a shopping list"*

6.4.6.4.3.1 Summary of parents' user evaluations

To summarise, the parents who completed the programme reported their children felt healthier, made new friends, felt fitter and happier since attending. Parents rated both the parent and child workshops and parent-only workshops highly and found then useful, although one parent thought they were poor. Since attending Y W8? 91% of parents felt confident or very confident in managing their child's weight in the future and most parents reported that other members of their family had made changes to a healthier lifestyle also.

6.4.6.4.4 Evaluation of data from non-starters / non-completers

Families who did not start the programme (n=7) and those that did not complete the programme (n=26) were followed up to ascertain their reasons for not continuing on the Y W8? programme. Initially families were contacted by telephone and if families did not respond they were sent a feedback form and stamped addressed envelope in the post. (The non-starter and non-completer feedback forms are in appendices 32 and 33). Table 6.24 shows the response rate and method for the non-starters and non-completers.

Table 6.24 Response rate and method for non-starters and non-completers

	Total number	Number of responders	Response method
Non-starters	7	3	Telephone (n=1) Postal feedback (n=2)
Non-completers	26	15	Telephone (n=9) Postal feedback (n=6)

Analysis was undertaken to ascertain if those who dropped out of the programme were systematically different from those who completed the programme by comparing the referral method and baseline characteristics (table 6.5).

Most noticeably, only 5 of the 33 families (15%) who self-referred dropped out and no families who were referred from the AWMS failed to complete. The rest of the families who dropped out (85%) had been referred in by a health professional. Although these are small numbers, the data suggests that responding to a poster, flyer or publicity in the

media is a measure of motivation towards their commitment to the programme. Families referred in by the AWMS may have had more realistic expectations about being part of a programme such as this.

The results from the telephone and postal feedback showing the reasons for non-starters and non-completers dropping out of the programme are shown in table 6.25.

Table 6.25 Reasons for non-starters and non-completers dropping out of the programme

Number of responders	Telephone feedback	Postal feedback
Non-starters (n=3)	Child refused to attend (n=1)	Child refused to attend (n=1) Childcare problems (n=1)
Non-completers (n=15)	Child thought it was boring (n=2) Not the right time to attend a programme (n=2) Wasn't what they thought it would be (n=1) Time was inconvenient (n=2) Childcare problems (n=2)	Not the right time (n=2) Time was inconvenient (n=2) Childcare problems (n=2)

Although small numbers make the data difficult to analyse there were a number of contributory factors for those dropping out including it not being the right time for families to start on a behaviour change programme, the time of the day being inconvenient and childcare problems for other children in the family who were not attending. The level of self-motivation may have also been a factor with 85% of families who dropped out being referred by a health professional.

6.5 Discussion

The number of participants recruited to this feasibility study was far greater than that suggested by the sample size calculation. This is because whilst the feasibility study was running the PCT agreed substantive funding to continue delivery of the service, and required more programmes to be delivered across the borough of Telford. This assured the future of the programme and gave the opportunity for more data to be collected allowing a richer analysis to be undertaken.

The feasibility study met the aims it set out to achieve. There was a significant positive effect on child BMI z-score and parent BMI in the short-term (3 months post-baseline). At post-assessment (3 months) children's BMI z-score showed a significant reduction of -0.12 (95% CI: -0.14 to -0.09, $p < 0.0005$, n=87). Ten children moved from being in the obese category to the overweight category, and five children moved from being overweight to normal weight. Parents significantly reduced their BMI at post-assessment by -0.44 kg/m^2 (95% CI: -0.68 to -0.21, $p < 0.005$, n=74). Overweight and obese parents also significantly reduced their BMI at post-assessment by -0.50 kg/m^2 (95% CI: -0.29 to -0.71, $p < 0.0005$, n=65). Positive changes in both children and parents weight status demonstrate the intervention had the desired effect of changing family behaviour, rather than changes being made just for the child and potentially singling them out.

In the longer-term (9 months post-baseline), children continued to improve their BMI z-score reduction; -0.15 (95% CI: -0.20 to -0.11, $p < 0.0005$, n=87). Nine children moved from being in the obese category to the overweight category, and eight children moved from being overweight to normal weight. In addition, three children achieved a clinically significant reduction of at least -0.5 BMI z-score. These results demonstrate the healthy behaviour changes made during the programme were continued after the programme had finished. At 9 months post-baseline parents also improved on the BMI reduction seen at post-assessment (-0.85 kg/m^2, 95% CI: -1.28 to -0.42, $p < 0.005$, n=74). Overweight and obese parents also improved their BMI at 9 months by -0.92 kg/m^2 (95% CI: -0.53 to -1.32, $p < 0.0005$, n=65).

The next aim was to test the feasibility of the operational procedures of the programme. The study allowed the researcher to deliver, assess and make changes, where necessary, to all operational aspects of the programme. For example, recruitment procedures from other health professionals were improved by the development of new referral forms and enabling GPs to refer electronically. Self-referral was enhanced by developing posters to be displayed in GP surgeries, community centres and leisure centres, and using case studies of successful families in the local media to stimulate interest. During delivery of the weekly programme fruit and water were offered to the group as many of the children came straight from school and were hungry, and this also enabled the Y W8? mentor to

role model and encourage healthy eating and drinking behaviours. Other problems such as gaining access to the classroom being used for the workshop in time for the room to be set up correctly, and making sure the sports hall equipment cupboard was unlocked, were also solved during this feasibility study. A number of changes in the intervention and evaluation procedures were made as a result of the feasibility trial. These are presented in chapter 7 table 7.1.

The graffiti wall, Y W8? user evaluation and interviews with parents were used to explore and assess the acceptability of the programme to families. On the whole both children and parents felt positive about the programme, finding the workshops useful and rating the physical activity sessions highly. Sixty-five percent of children and 91% of parents felt confident or very confident in managing their own or their child's weight in the future, and most parents reported that other members of their family had made changes to healthier lifestyle also.

The next aim was to test a number of hypotheses related to improving health behaviours and health status. The results of the secondary outcomes were important in this analysis. Children's self-esteem improved significantly over the duration of the programme. A small positive correlation was seen between change in BMI z-score and change in average self-esteem score and change in global self-worth, with increases associated with improvements in BMI z-score. This is similar to Wadden and colleagues (1990) who found significant increases in self-esteem. However, Epstein et al. (1998) comment that 'research to date suggests that improvement in self-esteem in obese children in treatment may be better accounted for by nonspecific treatment effects than by improvement in weight status' (p.564). In this study the BCT's; 'Prompt focus on past success', 'Provide feedback on performance', and 'Provide rewards based on effort and progress', as well as 'Provide rewards based on successful behaviour', would have all influenced improvements in children's self-esteem.

Children and parents significantly increased their score of how important physical activity was to them, and both significantly increase the number of days they achieved the recommended level of activity. A small positive correlation was seen with increases in how important physical activity was to children being associated with improvements in BMI

z-score. There was no correlation between either children or parents increase in physical activity levels and improvements in their weight status.

The amount of fruit and vegetables children consumed also increased significantly. However, there was no correlation between children's increase in fruit and vegetable consumption and beneficial changes in their BMI. The Healthy Family Behaviours Questionnaire was used to gain further insight into the participants eating and activity behaviour and provided a measure of programme fidelity. A significant improvement was reported across all themes; 91% of parents reported improvements in food and drink, 89% reported improvements in exercise behaviour, 69% of parents improved behaviours related to family behaviours and 78% reported improvements in positive parenting. A small positive correlation was associated with increases in the 'Family behaviour' themes with improvements in BMI z-score. There was no correlation between overweight and obese parents reported improvements in healthy family behaviours and improvements in their own BMI.

The use of a mixed-methods approach in this study has led to a greater insight into the effects of the programme than would have been provided by just using quantitative or qualitative methods alone. The quantitative data has provided evidence of the beneficial effects of the programme on children and parental health status and reported health behaviours. The qualitative data has been used to support this and 'illustrate' (Bryman 2006) the findings from the quantitative data. This enhances the validity of the findings and leads to a greater insight and understanding of the family's experiences, opinions of each aspect of the programme and brings to light any concerns they had.

The results of both the process and outcome evaluation of this feasibility study indicate the intervention was successful in supporting family's with overweight and obese children to change their eating and exercise behaviours. Despite the positive results from this study, it is not possible to conclude that the programme is effective as there was no control group. The feasibility study did, however, demonstrate that an RCT would be viable and useful and provided data regarding the likely effect size of the primary outcome measure, BMI z-score, for a future RCT. This RCT is reported in chapter 7.

Chapter 7 Study 2 – Pragmatic randomised controlled trial

7.1 Introduction

This chapter documents the RCT of the 'Y W8?' childhood obesity treatment programme. In line with the MRC framework for evaluating complex interventions (Craig et al. 2008) the feasibility study was completed and adjustments made prior to implementing the pragmatic RCT. The RCT was undertaken to provide high quality evidence that can be assessed in terms of effectiveness and how the intervention works, as suggested by Craig et al. (2008). A pragmatic RCT was chosen as it provides a balance between the traditional RCT and observational studies. Traditional RCTs are often far from routine clinical practice and their external validity can be questionable, whereas an observational study that assesses outcomes under normal service conditions may lack internal validity (Hotopf 2002). Pragmatic RCTs are also often utilised for complex interventions (Hotopf 2002). For the RCT evaluation took place on both process and outcome measures and comprised both qualitative and quantitative data. The Consolidated Standards of Reporting Trials Statement (2010) (CONSORT statement) was used as a guide for reporting of this study (Schulz, Altman and Moher 2010).

7.2 Aims

The aims of the RCT were:

- To evaluate the short-term (after 12 weeks of the programme) effectiveness of the Y W8? programme on children's BMI z-score versus a no treatment waiting list control group
- To further evaluate the short-term (after 12 weeks of the programme) effects of the programme on children's BMI z-score and parents BMI
- To continue to investigate the acceptability of the programme to families
- To carry out further testing of a number of hypotheses related to improving health behaviours and health status

7.3 Methods

7.3.1 Study design

The RCT was designed as an individually randomised parallel group trial with a WLC group. Quantitative data was collected to assess improvements in health behaviours and health status. Qualitative data was also collected to explore the acceptability of the programme to families, their opinions regarding the content of the programme and ideas they had to improve the programme.

Whilst the children in the intervention group had their height, weight, self-reported physical activity levels, self-reported fruit and vegetable consumption and a measure of self-esteem recorded at the pre-assessment (figure 7.1), only height and weight was collected from the children in the control group (figure 7.2). It was decided to follow this protocol so the control group followed the pathway of a 'no treatment' group as closely as possible. The added advantages of following this approach was that the control group would not be contaminated by having already completed the other measures, their expectations about what the programme included would not be raised, and there should be no reactive effect (Campbell and Stanley 1963). By following this protocol it was also hoped this would assist in reducing the number of drop-outs from the control group as they would not feel burdened by the questionnaires.

The control group was followed up at 12 weeks (the length of the intervention), and then invited to start the programme. Although taking the control measures at 9 months post-baseline would have enabled comparison of longer term follow-up data the PCT hosting and funding the study regarded 9 months too long to wait for the programme when the resources were available for them to start after a 12 week waiting period. Previous research from Rudolf et al. (2006) showed children referred to hospital outpatient clinics without a specific intervention increased their BMI z-score by 0.2 over a 3 to 6 month period. This data demonstrates children's BMI status continues to get worse when they are left without support so ethical considerations suggest it is clinically appropriate to offer the treatment programme as soon as it is available.

7.3.2 Inclusion and exclusion criteria

The criteria followed the same protocol as the feasibility study. Please see section 6.3.2 for further information.

7.3.3 Procedure for recruitment of families

Families were recruited using the same mechanisms as the feasibility study: referral from their GP, school nurse or other health professional and self-referral in response to local media. In addition, local data gathered from the NCMP was used to identify families with children in year 6 who had a BMI >91st percentile. The parents of these children were sent a letter informing them about the programme and inviting them to contact the programme to book an appointment with a Y W8? mentor to assess their eligibility for inclusion.

As per the protocol for the feasibility study (section 6.3.3), on referral families were sent an information pack which contained information on the location, day and time of the programme, the programme content, an application form and a stamped addressed envelope. Families were asked to complete the application form and send the form back to confirm their place. On receipt of the application form eligible families were contacted to arrange their pre-programme assessment. Families who were not eligible were offered other options dependent on their needs. Families who failed to return the application forms were contacted, where possible, to offer advice, support and sign-posting to other services as necessary.

At their pre-assessment families were given information describing the RCT (appendices 36 and 37) and asked to complete the child assent and parent consent forms (appendices 38 and 39). All children who met the criteria were offered a place in either the intervention or control group and non-overweight siblings in the age range were invited to attend the programme when applicable. Both parents were invited to attend.

7.3.4 Procedure for randomisation

Families were randomised, rather than individual children, to ensure those families with more than one eligible child were in the same group. Families were randomly allocated, in equal numbers, to the intervention group or a 12 week WLC group. Families were recruited and randomised in five cohorts. Randomisation was performed by a member of the PCT Health Improvement team who was not involved in the delivery of the programme. Each family was given an identification number and computer-generated random numbers were used to allocate them to a group. The programme began within two weeks of randomisation. It was not possible to blind families, the researcher or the Y W8? mentor to the group families were in. This lack of blinding could result in bias. For example, inadvertent encouragement to families in the intervention group to give favourable answers at their post-intervention assessment. However, due to the nature of the intervention and the fact that all anthropometric data was being collected by the very small team (researcher and Y W8? mentor) who were also delivering the programme, it was not possible to use blinding.

7.3.5 Sample size

For the purpose of sample size estimation the primary outcome of this study was change in BMI *z*-score from baseline to the end of the programme (12 weeks). The study was powered using the data from the feasibility study described in chapter 6. Based on a 1-sided test with a mean difference of -0.12, a significance level of 0.05, a power of 0.80 (as recommended by Cohen 1992) and allowing for a 30% drop-out the sample size required was 59 in each group.

7.3.6 Ethical approval

Research and development and ethical approval was received from Telford and Wrekin PCT, Shropshire NRES and Coventry University for all aspects of the development and implementation of the programme. (NRES number 06/Q2601/24). (See appendices 21, 22 and 23).

7.3.7 Procedure for delivery of the Y W8? Programme

The RCT began in January 2010 and finished in July 2011 and five groups received the programme in this time. The 12 week programme was delivered by trained weight loss mentors from the PCT's obesity services team (Y W8? mentor) and trained physical activity instructors. Each programme was delivered by one Y W8? mentor and one activity instructor. The workshop titles and topics covered in the workshop sessions are shown in table 6.1. The intervention was the same as that described in sections 6.3.6 and 6.3.7 with a small number of changes that are detailed in table 7.1.

Table 7.1 Changes made to the delivery of the Y W8? programme for the RCT

Activity	Changes made	Reasoning
Week 2 parents session	'Introduction to priorities' section added	A reflection tool to focus parents on what is important to them
Week 3 parents session	'Taking responsibility' section added	To improve parents understanding of their role in making changes and their understanding of being a role model
Week 6	Half-term review offered to families	To re-cap sessions and ensure understanding of programme content (height and weight measures not taken), and to increase self-efficacy
Week 7 parents session	1-2-3 activity added to Self-esteem and confidence activity	To assist with understanding of the activity and boost self-esteem
Eatwell plate	Eatwell plates for specific BME groups sourced	To support BME families accessing the programme and assist in their understanding of a healthy balanced diet
Y W8? 2 Get Cooking Sessions	Offered in half-term also	To increase the number of families able to access the session and increase families confidence in cooking food from fresh
Gifts	Rucksacks were changed	A different style of rucksack was sourced that could turned around so the logo could be hidden if the child wished (based on feedback received from the feasibility study)
Gifts	Pedometers were no longer given out	Unable to source good quality pedometers at a reasonable price
Y W8? Activ8! Session	In addition to the gym session a 'Zumbatomic' session was offered	More children and families were wishing to access a variety of sessions
Y W8? Activ8! session	In addition to the gym session a martial arts session was offered	More children and families were wishing to access a variety of sessions

7.3.8 Outcome evaluation measures

During weeks one and twelve the families met with their Y W8? mentor to have their pre- and post-measurements recorded regardless of whether they were in the intervention or control group. The evaluation measures for the intervention and control groups are shown

in figures 7.1 and 7.2. The pre- and post-outcome evaluation measures used for the intervention group are the same as those used in the feasibility study (figure 6.1).

Figure 7.1 Outcome evaluation measures for the intervention group of the RCT

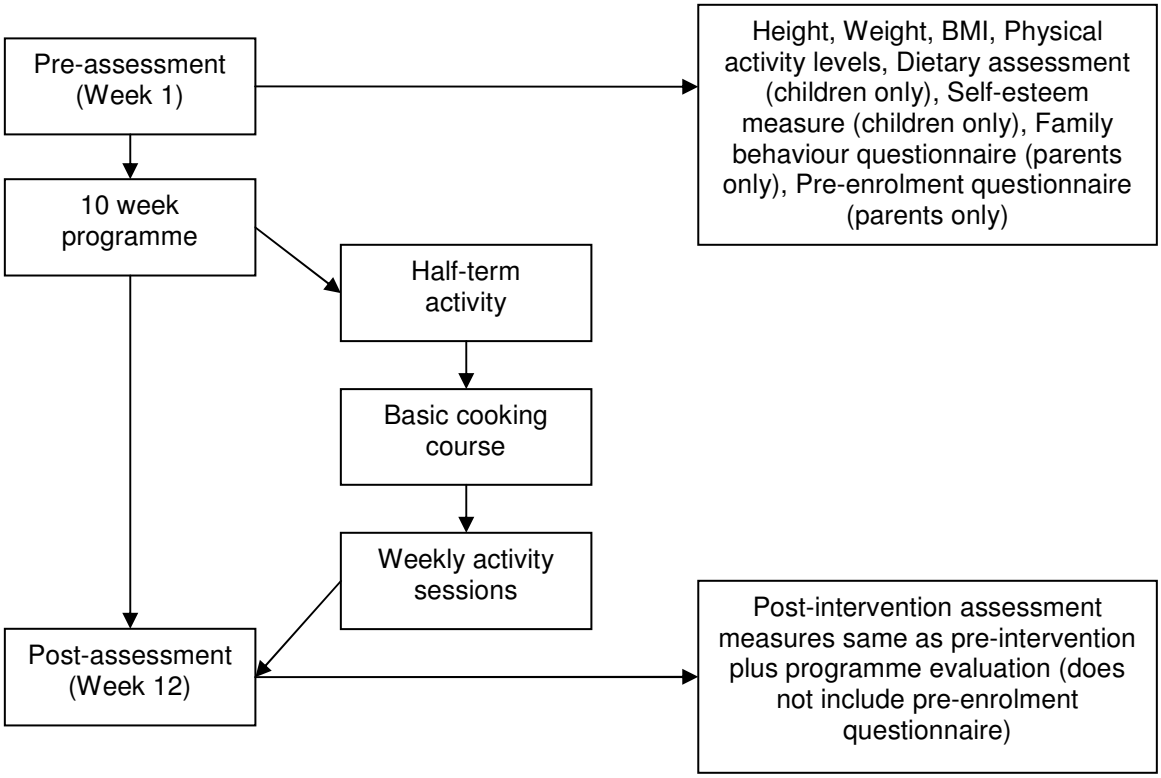
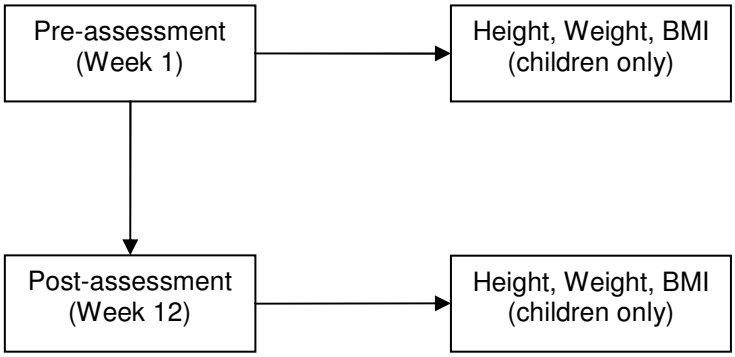


Figure 7.2 Outcome evaluation measures for the control group of the RCT



7.3.8.1 Measuring BMI

At the pre- and post-assessment children and parents had their height and weight recorded to calculate their BMI. Only the children's height and weight was measured for those in the control group. The protocol for measuring BMI was the same as that documented in section 6.3.8.1.

7.3.8.2 Children's self-esteem

Self-esteem was measured using a shortened version of the SPPC with the questionnaire entitled 'What I am Like' (Harter 1985) (appendix 24) as described in section 6.3.8.2. The amended version of the questionnaire was observed to be acceptable to children during the feasibility study with all children being able to complete the questionnaire with limited guidance. The 24 item amended version of the questionnaire included the domains of social acceptance, athletic competence, physical appearance and global self-worth. The scales of scholastic competence and behavioural conduct were removed as they were least relevant to the outcomes of the programme.

7.3.8.3 Children's and parents' physical activity measures

Physical activity levels were measured using the protocol described in section 6.3.8.3. Observations from the feasibility study demonstrated that the questions chosen were easy to complete and acceptable for both children and parents. The questions were selected as a performance indicator to see if individuals were achieving the recommended current physical activity targets for their age group.

7.3.8.4 Children's fruit and vegetable consumption

Children completed a 3 day food diary - 'Y W8? Nutrition Check' (appendix 26), and this was used to assess the average number of portions of fruit and vegetables consumed over the three days using the protocol described in section 6.3.8.4. In this study beans and pulses were counted as a 'fruit and veg' portion.

7.3.9 Process evaluation measures

7.3.9.1 Register of attendance

A weekly register of attendance was kept for every cohort. To be defined as having completed the programme the same guideline was used as in the feasibility study; families had to attend at least seven of the twelve sessions and must have attended the pre- and post-assessment sessions. The number of families dropping out of the programme was recorded for both the intervention and control groups and, where possible, their reason for dropping out was obtained.

7.3.9.2 Programme fidelity measures

7.3.9.2.1 Healthy family behaviours questionnaire

Healthy family behaviours were assessed using the locally developed Healthy Family Behaviours Questionnaires used in the feasibility study (appendix 27). The questionnaires were completed by the parents (see section 6.3.9.2.1 for further information).

7.3.9.2.2 Y W8? mentor session content evaluation (fidelity) sheet

Each week (excluding weeks 1, 6 and 12), the Y W8? mentor completed a session evaluation sheet feeding back how the session went, if the content was covered and any follow-up required (appendix 28). This ensured that all aspects of the workshops were covered and sections were not missed out. Any content that was not covered was included in a future week and a record kept of when this occurred. The evaluation sheets were reviewed weekly so that by the final group session all the content had been covered correctly.

7.3.10 Post-programme evaluation by parents and children

In addition to the outcome evaluation measures described in section 7.3.8, children and parents were asked to complete a programme evaluation giving their views of many aspects of the programme.

7.3.10.1 Y W8? user evaluations

During the week 12 post-assessment administered by a Y W8? mentor, children were asked to complete the Y W8? children's user evaluation and parents the Y W8? parent's user evaluation. This was the same as the evaluation used for the feasibility study (appendices 30 and 31). The evaluation included questions on the length of the programme, ratings of the delivery of workshops, staff knowledge and weekly handouts and changes they have made since starting the programme. There were also questions on the content of the workshops and how confident they felt in using the information they had been given.

7.3.10.2 Questionnaires for non-starters / non-completers

Families who did not complete the programme, including those in the intervention and control groups, were contacted to find out the reason they did not complete and to gain feedback on the programme when appropriate. Questionnaires were either completed through a telephone interview with the Y W8? mentor or sent to families to complete and return. The questionnaires can be found in appendices 32 and 33).

7.3.11 Evaluation hypotheses and planned analysis

The primary outcome measure was change in children's BMI z-score from pre-assessment to post-assessment (12 weeks), which was the same as the feasibility study. In addition, between group changes (intervention and control) were analysed to evaluate the effectiveness of the intervention. As per the feasibility study, there were also secondary outcomes for those who had been in the intervention group to measure the success of the childhood obesity treatment programme: improvement in children's self-esteem, increase

in children and parents physical activity levels, and increase in children's fruit and vegetable consumption and improvement in healthy family behaviours. The hypotheses and planned analysis are shown in table 7.2.

Table 7.2 Primary and secondary outcomes with hypotheses to test and planned analyses for the RCT

Number	Hypotheses	Outcomes	Planned analyses
Primary outcome - RCT			
1	There will be a difference in the change in children's BMI z-score when comparing children in the intervention group with those in the no treatment waiting list control group	BMI *z*-score	ANOVA
Primary outcome – Intervention group only			
2	Overweight and obese parents who complete the programme will decrease their BMI	BMI	Pre- post test of difference
3	Overweight and obese parents who make the most improvement in their BMI will have children who achieve the greatest improvement in their BMI z-score		Correlation analysis / Multiple regression
Secondary outcomes			
4	Children who complete the programme will increase their self-esteem	Self-esteem	Pre- post test of difference
5	Children who report the greatest increase in self-esteem will show the greatest improvements in their BMI z-score		Correlation analysis / Multiple regression
6	Children who complete the programme will increase their physical activity levels	Self-reported physical activity	Pre- post test of difference
7	Children who increase their activity levels the most will have the greatest improvements in BMI z-score		Correlation analysis / Multiple regression
8	Children who improve how important physical activity is to them the most will have the greatest improvements in BMI z-score		Correlation analysis / Multiple regression
9	Overweight and obese parents who increase their activity levels the most will have the greatest effect on their own BMI		Correlation analysis / Multiple regression
10	Parents who make the most improvements in their activity levels will have children who report the greatest improvements in activity levels also		Correlation analysis / Multiple regression
11	Children who complete the programme will improve their fruit and vegetable consumption	Self-reported fruit and vegetable consumption	Pre- post test of difference

Table 7.2 (Cont'd) Primary and secondary outcomes with hypotheses to test and planned analyses for the RCT

Number	Hypotheses	Outcomes	Planned analyses
12	Children who increase the amount of fruit and vegetables they consume the most will have the greatest beneficial effect on their BMI z-score		Correlation analysis / Multiple regression
Process evaluation measure			
13	Families completing the programme will improve their reported healthy family behaviours	Healthy family behaviours	Pre- post test of difference
14	Parents reporting the greatest changes in healthy family behaviours will have the most beneficial effect on their child's BMI z-score		Correlation analysis / Multiple regression
15	Overweight and obese parents reporting the greatest changes in healthy family behaviours will have the greatest improvements in their own BMI		Correlation analysis / Multiple regression

7.4 Results

The following terminology is used throughout the results section. This terminology is similar to the feasibility study with adjustments made for the presence of the control and intervention groups;

- Non-starters – intervention group, attended for a pre-assessment but did not start the programme
- Non-completers – intervention group, did not complete at least 7 of the sessions and/or did not have a post-assessment
- Completers – intervention group, attended at least 7 out of the 12 sessions including the post-assessment session
- Control completer – control group, attended for a pre-assessment and post-assessment
- Control non-completer – control group, did not attend post-assessment

7.4.1 Characteristics of participants

One hundred and fifty-seven children were assessed for eligibility with one hundred and fourteen families being recruited to the RCT. This is slightly less than that required as calculated by the sample size calculation. However, the calculation allowed for a 30% drop-out rate and the actual drop-out rate was only 19% from the intervention group and 6% from the control group. Therefore, this study was adequately powered.

Families were randomised to the intervention group or a WLC group as described in section 7.3.4. After being assessed for eligibility families were randomised to either the intervention or control group. Families were then asked to attend the initial assessment, and were told which group they were allocated to after the assessment. Figure 7.3 displays the flow of children through the study. There are more children than parents in the intervention group as some parents brought more than one child. Figure 7.4 displays the number of children attending for a pre-assessment (i.e. randomised) and their recruitment method. The recruitment method was not taken account of in randomisation. ('AWMS' denotes 'Adult weight management service' and refers to those children whose

parent was attending one of the adult weight management service offered by the PCT and was referred in from this service). In addition, to the recruitment methods used in the feasibility study the RCT recruited families from the NCMP (i.e. families who had received a letter reporting their child was overweight or very overweight who had phoned in for support).

Figure 7.3 Flow of children through the RCT

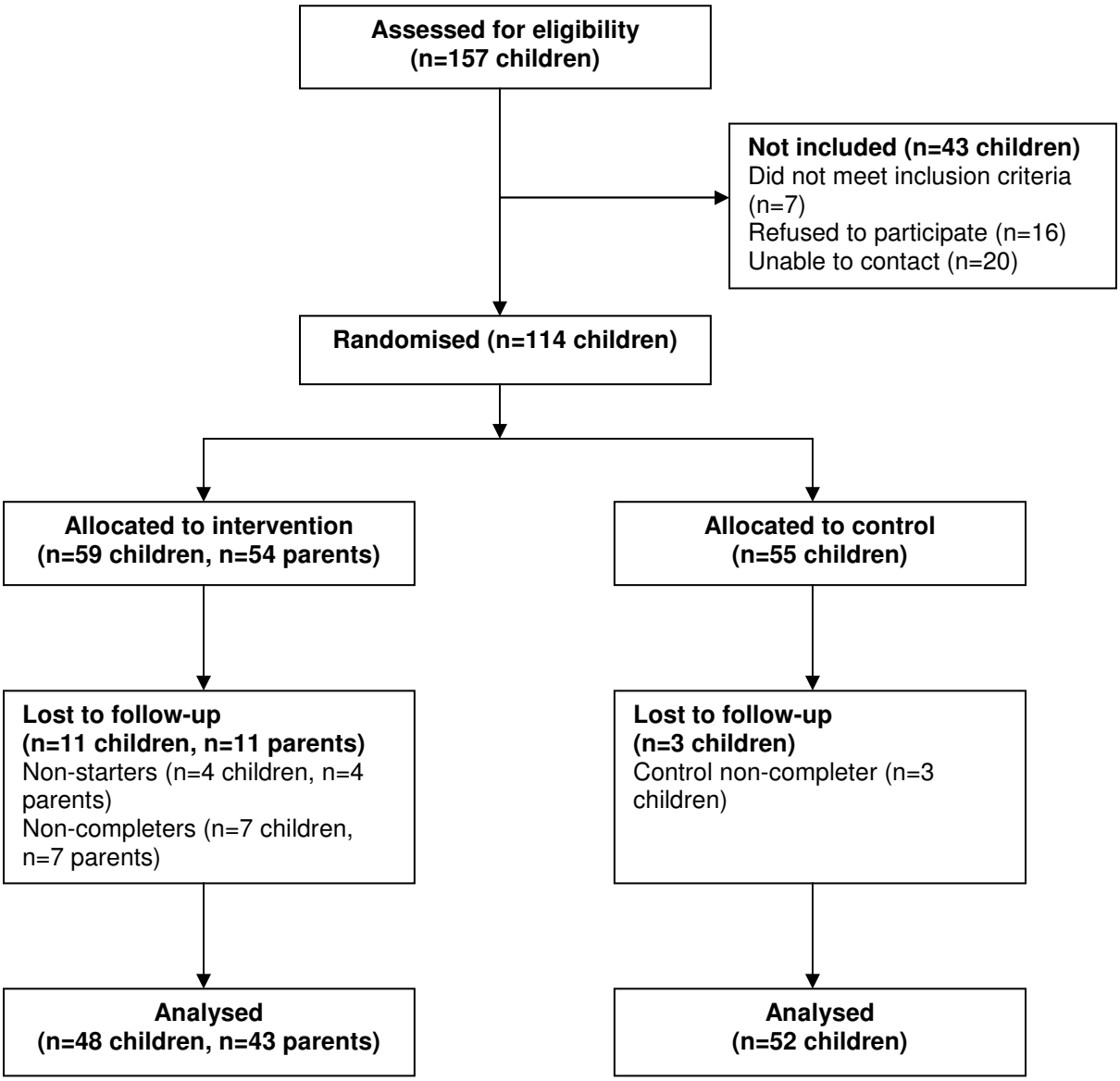


Figure 7.4 Number of children attending for a pre-assessment (i.e. randomised) and recruitment method (n=114)

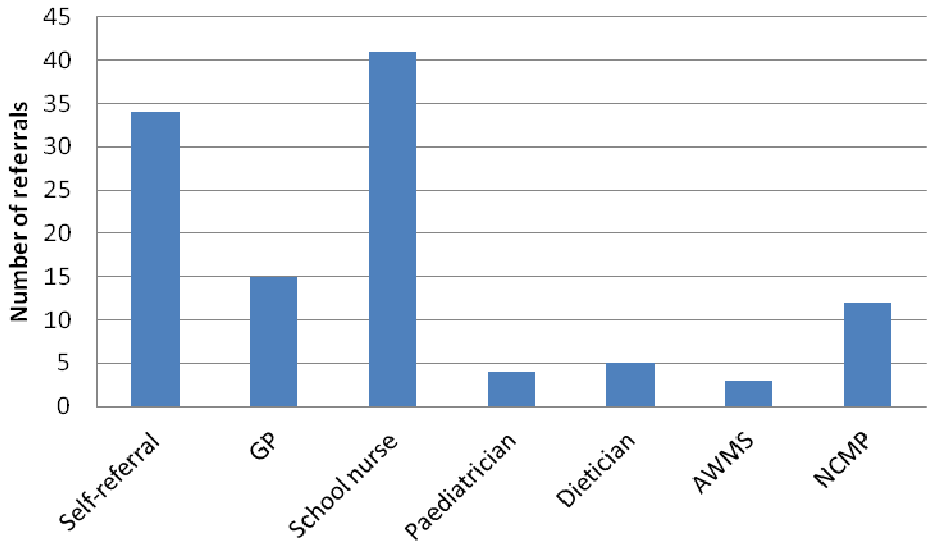


Figure 7.4 shows the greatest number of referrals were received from the school nurses, with a large number of self-referrals also.

7.4.2 Pre-programme assessment data

Table 7.3 shows the baseline characteristics for all children and parents in the intervention group and all children in the control group.

Table 7.3 Baseline characteristics of children and parents in the RCT

		Control	Intervention	
		Children (n=55)	Children (n=59)	Parents (n=54)
Gender	Males	27 (49%)	27 (46%)	5 (9%)
	Females	28 (51%)	32 (54%)	49 (91%)
Age (years)	Mean (SD)	11.56 (1.45)	10.61 (1.67)	39.82 (8.39)
	Range	8.1 – 13.6	8.1 – 13.9	26.5 – 67.1
Ethnicity	White	49 (89%)	48 (81%)	49 (91%)
	Mixed	2 (4%)	6 (10%)	2 (4%)
	Asian	1 (2%)	5 (9%)	3 (5%)
	Black	3 (5%)	0 (0%)	0 (0%)
BMI classification (children)	Overweight	21 (38%)	24 (41%)	
	Obese	34 (62%)	35 (59%)	
z-score	Mean (SD)	2.09 (0.40)	2.09 (0.44)	
BMI (parents only)*	Not overweight or obese (n)			10 (19%)
	Overweight (n)			11 (21%)
	Obese class I (n)			9 (17%)
	Obese class II (n)			10 (19%)
	Obese class III (n)			13 (24%)

* 1 parent refused to be weighed.

Over half of the children in both the intervention and control groups were above the 98th centile for BMI and were therefore defined as obese (Cole, Freeman and Preece 1995). In nearly a quarter of the families the parent who was attending with the child in the intervention group was overweight, and nearly two-thirds of the parents were obese. The

table shows that 51% of the children in the control group, 54% of the children in the intervention group and 91% of the parents in the intervention group were female.

Analysis of the pre-assessment data for children in the control and intervention groups showed there was a significant difference at the $p < 0.05$ level between the groups for age at baseline: $F(1, 112) = 10.5$, $p = 0.002$, with the control group (M = 11.56, SD = 1.45) being older than the intervention group (M = 10.61, SD = 1.67). There were no other significant differences.

The baseline characteristics of children and parents in the intervention group who completed, did not start and did not complete are displayed in table 7.4.

Table 7.4 Baseline characteristics of intervention group (completers v non-starters v non-completers)

		Completers	Non-starters	Non-completers
Children (n)		(n=48)	(n=4)	(n=7)
Gender	Males	23 (48%)	1 (25%)	3 (43%)
	Females	25 (52%)	3 (75%)	4 (57%)
Age (years)	Mean (SD)	10.63 (1.53)	10.20 (2.17)	10.69 (2.50)
	Range	8.2 – 13.3	8.2 – 12.9	8.1 – 13.9
Ethnicity	White	40 (83%)	4 (100%)	4 (57%)
	Mixed	3 (6%)	0 (0%)	3 (43%)
	Asian	5 (11%)	0 (0%)	0 (0%)
	Black	0 (0%)	0 (0%)	0 (0%)
BMI classification	Overweight (n)	22 (46%)	0 (0%)	2 (29%)
	Obese (n)	26 (54%)	4 (100%)	5 (71%)
z-score	Mean (SD)	2.08 (0.45)	2.35 (0.31)	2.07 (0.45)
Parents (n)		(n=42)	(n=4)	(n=7)
Gender	Males	5 (12%)	0 (0%)	0 (0%)
	Females	38 (88%)	4 (100%)	7 (100%)
Age (years)	Mean (SD)	40.8 (7.76)	44.65 (12.84)	31.33 (3.39)
	Range	28.5 – 67.1	31.3 – 61.6	26.5 – 35.5
Ethnicity	White	40 (93%)	4 (100%)	5 (71%)
	Mixed	0 (0%)	0 (0%)	2 (29%)
	Asian	3 (7%)	0 (0%)	0 (0%)
	Black	0 (0%)	0 (0%)	0 (0%)
BMI *	Not overweight or obese (n)	6 (15%)	1 (25%)	3 (43%)
	Overweight (n)	9 (21%)	0 (0%)	2 (29%)
	Obese class I (n)	8 (19%)	0 (0%)	1 (14%)
	Obese class II (n)	9 (21%)	0 (0%)	1 (14%)
	Obese class III (n)	10 (24%)	3 (75%)	0 (0%)

* 1 parent refused to be weighed.

Table 7.4 shows for the children who completed the programme there was a near even split between males and females and those who were overweight and obese. In the small group of children who did not start the programme there were three females compared to one male, all were white and all were obese. In the children non-completers group four were female and three male, they were of either a white or mixed ethnicity and the majority were obese. Regarding the parents, the majority in all three groups were female and of white ethnicity. The completers had BMIs throughout the range, nearly half of the non-

completers were of a healthy weight and most of the non-starters had a BMI in the obese class III range.

One-way analysis of variance (ANOVA) was used to compare the children's pre-assessment data for completers and non-completers (including non-starters). There were no significant differences highlighted.

For the three children in the control arm who were lost to follow-up; two were white females in the overweight category, and one was a white male in the obese category.

7.4.3 Results of the RCT

7.4.3.1 Change in BMI z-score for children

A one-way ANOVA was undertaken to evaluate the short-term (3 month) effectiveness of the Y W8? programme on children's BMI z-score versus a no treatment WLC group. Hypothesis 1 was tested: 'There will be a difference in the change in children's BMI z-score when comparing children in the intervention group with those in the no treatment waiting list control group'. The results are shown in tables 7.5.

Table 7.5 Changes in children's BMI z-score from pre-assessment (0 months) to post-assessment (3 months) for control and intervention groups

	Control group (n=52)	Intervention group (n=48)	Mean difference (95% CI)	*p* value
Pre BMI z-score Mean (SD)	2.11(0.39)	2.08(0.45)		
Post BMI z-score Mean (SD)	2.12(0.39)	1.96(0.51)		
Change in BMI z-score Mean (SD)	0.01(0.06)	-0.11(0.10)	-0.12 (0.09 to 0.16)	<0.0005

Results of the analysis shows a significant difference in the mean change in BMI z-score between the control group (M = 0.01, SD = 0.06) and the intervention group, M = -0.11, SD

= 0.10; F (1, 98) = 54.04, at the $p < 0.0005$ level, with the control group increasing and the intervention group reducing their BMI z-score. The magnitude of the differences in the means (mean difference = -0.12, 95% CI: 0.09 to 0.16) was large (eta squared = 0.36).

Analysis was also carried out on the other anthropometric outcome measures recorded in the control and intervention groups; these are shown in table 7.6.

Table 7.6 Changes in children's anthropometric measurements from pre-assessment (0 months) to post-assessment (3 months) for control and intervention groups

	Control group (n=52)	Intervention group (n=48)	Mean difference (95% CI)	*p* value
Pre BMI Mean (SD)	29.34(5.71)	27.87(5.51)		
Post BMI Mean (SD)	29.74(5.76)	27.08(5.38)		
Change in BMI Mean (SD)	0.40(0.52)	-0.79(0.78)	1.19 (0.93 to 1.46)	<0.0005
Pre Weight Mean (SD)	65.23(17.93)	60.17(16.43)		
Post Weight Mean (SD)	67.46(18.15)	59.53(16.14)		
Change in Weight Mean (SD)	2.23(1.41)	-0.64(1.78)	2.87 (2.23 to 3.50)	<0.0005
Pre Weight z-score Mean (SD)	1.99(0.69)	2.07(0.71)		
Post Weight z-score Mean (SD)	2.03(0.67)	1.93(0.74)		
Change in Weight z-score Mean (SD)	0.03(0.08)	-0.14(0.10)	0.17 (0.13 to 0.20)	<0.0005
Pre Height Mean (SD)	1.48(0.10)	1.46(0.10)		
Post Height Mean (SD)	1.50(0.10)	1.47(0.10)		
Change in Height Mean (SD)	0.0154 (0.0082)	0.0132 (0.0077)	0.0022 (-0.0009 to 0.0054)	= 0.165
Pre Height z-score Mean (SD)	0.11(1.05)	0.59(0.95)		
Post Height z-score Mean (SD)	0.13(1.04)	0.57(0.95)		
Change in Height z-score Mean (SD)	0.0187 (0.1132)	-0.0156 (0.1235)	0.0343 (-0.013 to 0.081)	= 0.151

Results show significant changes in BMI ($p < 0.005$), weight ($p < 0.005$) and weight z-score ($p < 0.005$). The magnitude of the differences in the means (BMI mean difference = 1.19, 95% CI: 0.93 to 1.46, weight mean difference = 2.87, 95% CI: 2.23 to 3.50, weight z-score mean difference = 0.17, 95% CI: 0.13 to 0.20) was large (eta squared BMI = 0.45, weight = 0.45, weight z-score = 0.46). Changes in height and height z-score between the control and intervention groups were not significant, $p = 0.165$ and $p = 0.151$ respectively. Therefore, the changes observed in BMI z-score are not an artefact for changed height but attributable to a reduction in weight.

7.4.3.2 Change in BMI z-score for children - Intention-to-treat analysis

An intention-to-treat analysis was also conducted on the change in BMI z-score for children. Table 7.7 displays the change in BMI z-score from pre-assessment to post-assessment for the control and intervention groups.

Table 7.7 Changes in children's BMI z-score from pre-assessment (0 months) to post-assessment (3 months) for control and intervention groups – intention-to-treat analysis

	Control group (n=55)	Intervention group (n=59)	Mean difference (95% CI)	*p* value
Pre BMI z-score Mean (SD)	2.09(0.40)	2.09(0.44)		
Post BMI z-score Mean (SD)	2.10(0.40)	2.00(0.50)		
Change in BMI z-score Mean (SD)	0.01(0.06)	-0.09(0.10)	-0.10 (0.07 to 0.13)	<0.0005

As expected the results for the intention-to-treat analysis are more conservative. However, there was still a significant difference in the mean change in BMI z-score between the control group (M = 0.01, SD = 0.06) and the intervention group, M = -0.09, SD = 0.10; $F(1, 112) = 42.52$, at the $p < 0.0005$ level, with the control group increasing and the intervention group reducing their BMI z-score. The magnitude of the differences in the means (mean difference = -0.10, 95% CI: 0.07 to 0.13) was large (eta squared = 0.28).

7.4.3.3 Magnitude of change in BMI z-score

The magnitude of change in BMI z-score was determined for children in both the control and intervention group (table 7.8).

Table 7.8 Magnitude of change in BMI z-score for children in the control and intervention groups

Change in BMI z-score from baseline	Control group (n=52)	Intervention group (n=48)
Increase	30	4
No change	2	2
Decrease <0.25	20	38
Decrease ≥0.25 - <0.5	0	4
Decrease ≥0.5*	0	0

* Defined a clinically significant change (Reinehr and Andler 2004)

The results show that two children in both the control and intervention group did not change their BMI z-score. The clinically significant reduction of 0.5 BMI z-score suggested by Reinehr and Andler (2004) was not achieved by any children, regardless of their randomised group, by the end of the 12 weeks. The table shows a number of trends with more than half (58%) of the control group increasing their BMI z-score and 38% reducing it by less than 0.25 units. In comparison 88% of the intervention group reduced their BMI z-score, (80% by less than 0.25 units and 8% between 0.25 and 0.5 units), and 8% increased their BMI z-score.

A Chi-square test for independence indicated a significant association between control / intervention status and change in BMI z-score, X^2 (2, n=114) = 31.55, $p < 0.0005$, phi = 0.53.

Change in weight status was also explored by examining children's BMI and recording whether any children moved between the obese (BMI >98th centile), overweight (BMI >91st to <98th centile) and 'normal' (BMI <91st centile) categories (table 7.9).

Table 7.9 Change in category of overweight and obesity for children in the control and intervention groups

	Control group (n=52)	Intervention group (n=48)
OBESE at pre-assessment		
Stayed in obese category	32	25
Moved to overweight category	**1**	**1**
Moved to 'normal' weight category	0	0
OVERWEIGHT at pre-assessment		
Moved to obese category	2	1
Stayed in overweight category	16	15
Moved to 'normal' weight category	**1**	**6**

Table 7.9 shows for the control group 2 children changed category over the 12 week period; 1 moved from being obese to overweight and 1 moved from being overweight to 'normal' weight. In the intervention group 7 children changed category over the 12 weeks; 1 child moved from the obese to overweight category and 6 from being overweight to 'normal' weight.

7.4.4 Analysis of programme hypotheses – Intervention group only

To further evaluate the short-term (3 month) effects of the programme on children's BMI z-score and parents' BMI, and to carry out further testing of a number of hypotheses related to improving health behaviours and health status analysis was undertaken of the pre- and post-assessment results for the intervention group only.

7.4.4.1 Children's measurements – Intervention group only

The measures of body composition for the children who completed are shown in table 7.10.

Table 7.10 Changes in children's measurements from pre-assessment (0 months) to post-assessment (3 months) for completers – intervention group only

	0 months Mean (SD) (n=48)	3 months Mean (SD) (n=48)	0-3 month change (n=48)	
			Mean (95% CI)	*p* value
BMI z-score	2.08(0.45)	1.96(0.51)	-0.11 (-0.14 to -0.08)	<0.0005
BMI (kg/m^2)	27.87(5.51)	27.08(5.38)	-0.79 (-1.01 to -0.57)	<0.0005
Height (m)	1.46(0.10)	1.47(0.10)	0.013 (0.011 to 0.015)	<0.0005
Height z-score	0.59(0.95)	0.57(0.95)	-0.016 (-0.052 to 0.02)	0.39
Weight (kg)	60.17(16.43)	59.53(16.14)	-0.64 (-1.15 to -0.12)	0.017
Weight z-score	2.07(0.71)	1.93(0.74)	-0.136 (-0.17 to -0.11)	<0.0005

The BMI z-score shows a significant reduction from pre-assessment by -0.11 (95% CI: -0.14 to -0.08, $p < 0.0005$, n=48) to post-assessment (3 months). This is very similar to the results achieved in the feasibility study; reduction of -0.12 (95% CI: -0.14 to -0.09, $p < 0.0005$, n=87). Analyses of the individual children's change in BMI z-score showed four children increased their BMI z-score, for two children it stayed the same and forty-two children reduced their BMI z-score. The programme did not adversely affect linear growth. Height increased significantly, as would be expected (table 7.10). Height expressed as a z-score did not change significantly.

7.4.4.2 Children's measurements – Intervention group only – Intention-to-treat analysis

An intention-to-treat analysis was also conducted on the measures of body composition for children in the intervention group only. Table 7.11 displays the results.

Table 7.11 Changes in children's measurements from pre-assessment (0 months) to post-assessment (3 months) for completers – intervention group only - intention-to-treat analysis

	0 months Mean (SD) (n=59)	3 months Mean (SD) (n=59)	0-3 month change (n=59)	
			Mean (95% CI)	*p* value
BMI z-score	2.09(0.44)	2.00(0.50)	-0.09 (-0.12 to -0.07)	<0.0005
BMI (kg/m^2)	28.07(5.60)	27.43(5.53)	-0.64 (-0.84 to -0.44)	<0.0005
Height (m)	1.46(0.10)	1.47(0.10)	0.011 (0.008 to 0.013)	<0.0005
Height z-score	0.56(0.95)	0.55(0.96)	-0.013 (-0.042 to 0.016)	0.38
Weight (kg)	60.39(16.63)	59.87(16.41)	-0.52 (-0.94 to -0.10)	0.017
Weight z-score	2.08(0.71)	1.97(0.74)	-0.111 (-0.138 to -0.083)	<0.0005

The BMI z-score shows a significant reduction from pre-assessment by -0.09 (95% CI: -0.12 to -0.07, $p < 0.0005$, n=59) to post-assessment (3 months). This is similar to the intention-to-treat analysis conducted in the feasibility study.

7.4.4.3 Parents' measurements – Intervention group only

The measures of body composition for the parents are displayed in table 7.12. These results were analysed to test hypothesis 2; 'overweight and obese parents who complete the programme will decrease their BMI', and hypothesis 3 'overweight and obese parents who make the most improvement in their BMI will have children who achieve the greatest improvement in their BMI z-score'.

Table 7.12 Changes in parents' measurements from pre-assessment (0 months) to post-assessment (3 months) for completers – intervention group only

	0 months Mean (SD) (n=42)*	3 months Mean (SD) (n=42)*	0-3 month change (n=42)*	
			Mean (95% CI)	*p* value
BMI (kg/m^2)	34.36(10.24)	33.76(10.05)	-0.59 (-0.97 to -0.22)	0.003
Weight (kg)	92.51(27.16)	90.45(26.22)	-2.06 (-3.50 to -0.62)	0.006

* 1 parent refused to be weighed

Parents significantly reduced their BMI at post-assessment by -0.59 kg/m^2 (95% CI: -0.97 to -0.22, $p = 0.003$, n=42). This was greater than that achieved by the parents in the feasibility study, over the same 12 week period, where parents reduced their BMI by -0.44 kg/m^2 (95% CI: -0.68 to -0.21, $p < 0.0005$, n=74). Overweight and obese parents also significantly reduced their BMI at post-assessment by -0.72 kg/m^2 (95% CI: -1.15 to -0.30, $p = 0.001$, n=36). Again, these results improved upon that achieved by the overweight and obese parents in the feasibility study (mean BMI change = -0.50 kg/m^2, 95% CI: -0.29 to -0.71, $p < 0.0005$, n=65). There was no significant correlation between overweight and obese parents who make the most improvement in their BMI and improvements in BMI z-score of their children.

7.4.5 Secondary outcome results – Intervention group only

7.4.5.1 Children's self-esteem – Intervention group only

Children's self-esteem was measured using an amended version of the Self-Perception Profile for Children (SPPC) (Harter 1985). Analysis of the results tested hypothesis 4; 'children who complete the programme will increase their self-esteem' and hypothesis 5; 'children who report the greatest increase in self-esteem will show the greatest improvements in their BMI z-score'. The results are shown in table 7.13.

Table 7.13 Change in children's self-esteem scores from pre-assessment (0 months) to post-assessment (3 months) – intervention group only

	0 months Mean (SD) (n=48)	3 months Mean (SD) (n=48)	0-3 month change (n=48)	
			Mean (95% CI)	*p* value
Social acceptance	2.99(0.75)	2.81(0.73)	0.19 (0.03 to 0.34)	0.018
Athletic competence	2.72(0.69)	2.47(0.76)	0.25 (0.04 to 0.46)	0.021
Physical appearance	2.67(0.75)	2.25(0.80)	0.42 (0.25 to 0.59)	<0.0005
Global self-worth	3.05(0.67)	2.75(0.73)	0.30 (0.11 to 0.49)	0.003

Children's self-esteem changed significantly from baseline to 3 months for all of the 4 domains measured ($p < 0.05$) (table 7.13). The greatest change was seen in the domain 'Physical appearance' (0.42, 95% CI: 0.25 to 0.59, $p < 0.0005$, n=48). Further analysis showed three children recorded the same pre- and post-intervention score for the domain of social acceptance, three children for athletic competence, eight children for physical appearance and seven children for global self-worth.

The relationship between change in average self-esteem score and the four self-esteem domains and change in BMI z-score was investigated using Pearson product-moment correlation coefficient (table 7.14).

Table 7.14 Correlation between change in self-esteem scores and BMI z-score – intervention group only

	Pearson Correlation (n=48)	*p* value
Change in average self esteem score	0.104	0.482
Change in social acceptance score	-0.057	0.70
Change in athletic competence score	-0.053	0.719
Change in physical appearance score	0.306	0.034
Change in global self-worth score	0.063	0.672

A medium-sized positive correlation was found between change in BMI z-score with change in physical appearance (r=0.306, n=48, $p < 0.05$), with increases in scores associated with improvements in BMI z-score. No other correlations were significant (table 7.14).

7.4.5.2 Children's and parents' physical activity measures – Intervention group only

The results of the analysis of the children and parents physical activity measures are shown in tables 7.15 and 7.16 respectively. Analyses of the results were used to test the following hypotheses;

- Hypothesis 6: Children who complete the programme will increase their physical activity levels
- Hypothesis 7: Children who increase their activity levels the most will have the greatest improvements in BMI z-score
- Hypothesis 8: Children who improve how important physical activity is to them the most will have the greatest improvements in BMI z-score
- Hypothesis 9: Overweight and obese parents who increase their activity levels the most will have the greatest effect on their own BMI

- Hypothesis 10: Parents who make the most improvements in their activity levels will have children who report the greatest improvements in activity levels also

Table 7.15 Change in children's physical activity measures from pre-assessment (0 months) to post-assessment (3 months) – intervention group only

	0 months Mean (SD) (n=48)	3 months Mean (SD) (n=48)	0-3 month change (n=48)	
			Mean (95% CI)	*p* value
How important is physical activity to you? 0 = Not important at all, 10 = Extremely important	8.10(1.87)	8.67(1.43)	0.56 (0.02 to 1.11)	0.042
How many days a week (on average) do you spend doing the following? Total of 60 minutes on physical activity – at a 'moderate pace'	4.21(2.04)	5.33(1.66)	1.12 (0.54 to 1.69)	<0.0005
How many days a week (on average) do you spend doing the following? Total of 40 minutes on an activity that makes you sweat or out of breath	3.41(2.25)	4.59(1.69)	1.17 (0.45 to 1.90)	0.002

Children significantly increased their score of how important physical activity was to them when measured on a scale of 1 – 10 with 1 being not important at all and 10 being extremely important ($p = 0.042$). Children also significantly increased the number of days

per week they completed 60 minutes of physical activity ($p < 0.0005$) and significantly increased the number of days per week they took part in activity at an increased intensity ($p = 0.002$) (table 7.13). Further analysis showed nineteen children recorded the same pre- and post-intervention score for question 1, fifteen for question 2a and eleven for question 2b.

Table 7.16 Change in parents physical activity levels from pre-assessment (0 months) to post-assessment (3 months) – intervention group only

	0 months Mean (SD) (n=42)	3 months Mean (SD) (n=42)	0-3 month change (n=42)	
			Mean (95% CI)	*p* value
How important is physical activity to you? 0 = Not important at all, 10 = Extremely important	7.53(2.05)	8.28(1.78)	0.74 (0.10 to 1.39)	0.024
How many days a week (on average) do you spend doing the following? Total of 30 minutes on physical activity – at a 'moderate pace'	3.39(2.31)	4.34(2.30)	0.95 (0.23 to 1.67)	0.011
How many days a week (on average) do you spend doing the following? Total of 20 minutes on an activity that makes you sweat or out of breath	2.16(1.68)	3.19(2.05)	1.03 (0.40 to 1.65)	0.002

Results from the questionnaire showed parents also significantly increased their score of how important physical activity was to them ($p = 0.024$). Parents also reported a significant increase in the number of days per week they completed 30 minutes of physical activity at a moderate pace ($p = 0.011$) and significantly increased the number of days per week they took part in activity for 20 minutes at an increased intensity ($p = 0.002$) (table 7.16).

There were no significant correlations seen for the other hypotheses tested.

7.4.5.3 Children's fruit and vegetable consumption

Average daily fruit and vegetable consumption was gathered from the 3 day food diary as described in section 6.3.8.4. The results were used to test hypothesis 11; 'children who complete the programme will improve their fruit and vegetable consumption' and hypothesis 12; 'children who increase the amount of fruit and vegetables they consume the most will have the greatest beneficial effect on their BMI z-score'. The results are shown in table 7.17.

Table 7.17 Change in children's fruit and vegetable consumption from pre-assessment (0 months) to post-assessment (3 months) – intervention group only

	0 months Mean (SD) (n=33)*	3 months Mean (SD) (n=33)*	0-3 month change (n=33)*	
			Mean (95% CI)	*p* value
Fruit and veg consumption (portions/day)	1.65(0.72)	2.91(0.82)	1.26 (1.08 to 1.45)	<0.0005

* n is less due to not all children returning their diary and incomplete diaries

According to the 3 day food diary completed by the children fruit and vegetable consumption significantly increased from pre- to post-assessment ($p < 0.0005$) (table 7.17). Only one child reported the same amount of fruit and vegetables pre- and post-intervention. Analysis showed no significant correlation between improvements in the amount of fruit and vegetables consumed and improvements in BMI z-score.

7.4.5.5 Results of analysis of programme hypotheses

Results of the planned analyses are shown in table 7.18. Some of the data has been presented in previous sections. Children in the no treatment WLC group slightly increased their BMI z-score over the 12 weeks, this was not significant (0.01, $p = 0.209$, n=52).

Table 7.18 Results of planned analyses

Number	Hypotheses	Outcomes	Results
Primary outcome - RCT			
1	There will be a difference in the change in children's BMI z-score when comparing children in the intervention group with those in the no treatment waiting list control group	BMI *z*-score	There was a significant difference in change in BMI z-score between the control and intervention group, mean difference = -0.12 (95% CI: 0.09 to 0.16, F (1, 98) = 54.04, p < 0.0005), with the control group increasing and the intervention group decreasing their BMI z-score
Primary outcome – Intervention group only			
2	Overweight and obese parents who complete the programme will decrease their BMI	BMI	Overweight and obese parents significantly reduced their BMI at post-assessment by -0.72 kg/m^2 (95% CI: -1.15 to -0.30, p = 0.001, n=36)
3	Overweight and obese parents who make the most improvement in their BMI will have children who achieve the greatest improvement in their BMI z-score		No significant correlation
Secondary outcomes – Intervention group only			
4	Children who complete the programme will increase their self-esteem	Self-esteem	Children's self-esteem change significantly for all of the 4 domains measured; Social acceptance (0.19, 95% CI: 0.03 to 0.34, p = 0.018, n=48) Athletic competence (0.25, 95% CI: 0.04 to 0.46, p = 0.021, n=48) Physical appearance (0.42, 95% CI: 0.25 to 0.59, p < 0.0005, n=48) Global self-worth (0.30, 95% CI: 0.11 to 0.49, p = 0.003, n=48)
5	Children who report the greatest increase in self-esteem will show the greatest improvements in their BMI z-score		No significant correlation

Table 7.18 (Cont'd) Results of planned analyses

Number	Hypotheses	Outcomes	Results
6	Children who complete the programme will increase their physical activity levels	Self-reported physical activity	Children significantly increased their physical activity levels; Number of days a week they completed 60 minutes of physical activity (1.12, 95% CI: 0.54 to 1.69, $p < 0.0005$, n=48) Number of days a week they took part in activity at an increased intensity (1.17, 95% CI: 0.45 to 1.90, $p = 0.002$, n=48)
7	Children who increase their activity levels the most will have the greatest improvements in BMI z-score		No significant correlation
8	Children who improve how important physical activity is to them the most will have the greatest improvements in BMI z-score		No significant correlation
9	Overweight and obese parents who increase their activity levels the most will have the greatest effect on their own BMI		No significant correlation
10	Parents who make the most improvements in their activity levels will have children who report the greatest improvements in activity levels also		No significant correlation
11	Children who complete the programme will significantly improve their fruit and vegetable consumption	Self-reported fruit and vegetable consumption	Fruit and vegetable consumption significantly increased (1.26, 95% CI: 1.08 to 1.45, $p < 0.0005$, n=33)
12	Children who increase the amount of fruit and vegetables they consume the most will have the greatest beneficial effect on their BMI z-score		No significant correlation

Table 7.18 (Cont'd) Results of planned analyses

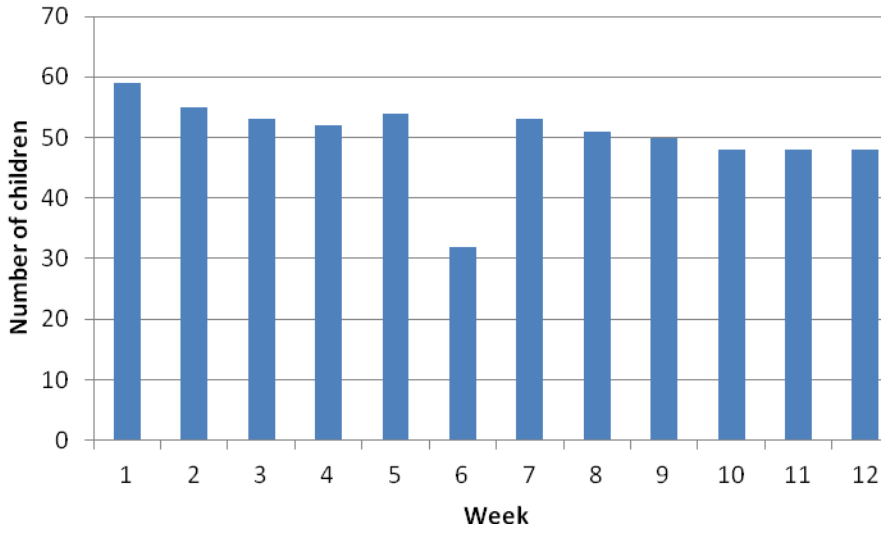
Number	Hypotheses	Outcomes	Results
Process evaluation measure			
13	Families completing the programme will improve their reported healthy family behaviours	Healthy family behaviours	Reported family behaviours improved significantly for all themes; Food and drink (0.51, 95% CI: 0.36 to 0.67, $p < 0.0005$, n=48) Exercise (0.49, 95% CI: 0.33 to 0.64, $p < 0.0005$, n=48) Family behaviour, (0.14, 95% CI: 0.51 to 0.23, $p = 0.003$, n=48) Positive parenting (0.52, 95% CI: 0.36 to 0.68, $p < 0.0005$, n=48)
14	Parents reporting the greatest changes in healthy family behaviours will have the most beneficial effect on their child's BMI z-score		No significant correlation
15	Overweight and obese parents reporting the greatest changes in healthy family behaviours will have the greatest improvements in their own BMI		No significant correlation

7.4.6 Process evaluation measures – Intervention group only

7.4.6.1 Register of attendance

A register of attendance was kept for each week of the programme for all groups. Figure 7.5 shows the weekly attendance at Y W8? for all intervention groups. Figure 7.6 displays the percentage attendance against the total still in the programme at that week.

Figure 7.5 Children's weekly attendance at Y W8? for all intervention groups



Similar to the feasibility study, figure 7.5 shows children's attendance at the group gradually decreased as the programme progressed. Attendance at week 6 was low as it was the half-term session and some families were away on holiday. In contrast to the feasibility study, there was a good attendance at week 5, even though it was the last day before the half-term break. Information regarding reasons why families did not start the programme or did not complete the programme is given in section 7.4.7.3.

Figure 7.6 Percentage of children attending against the total still in the programme at that week for all intervention groups

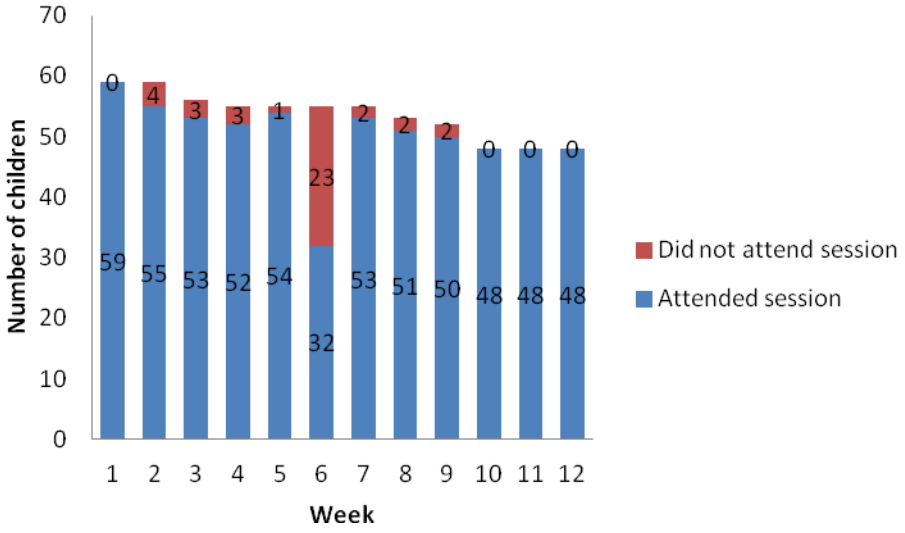


Figure 7.6 shows how the attendance at weekly sessions gradually decreased as the programme progressed. In contrast to the feasibility study there was no particular drop out between weeks 6 and 7, over the half-term break. This might be due to the half-term review that was introduced as part of the protocol for the RCT. The aim of this session was to re-cap the workshops and ensure understanding of programme content. Although not all families attended this session (58%), it was higher than the attendance at the week 6 activity included in the feasibility study (49%), and provided a good means of engaging with families and providing support. Eighty-seven percent of families who remain engaged after half-term, (attended week 7), completed the programme. For all other weeks, (excluding week 6), the attendance level ranged from 100% to 93%.

7.4.6.2 Programme fidelity measures

7.4.6.2.1 Healthy Family Behaviours Questionnaire

The Healthy Family Behaviours questionnaire was completed by the parents. Parents bringing more than one child were asked to complete the questionnaire for each child. The 25 statements included in the questionnaire were grouped into themes; food and

drink, exercise, family behaviour and positive parenting. The questionnaires were analysed to test the hypothesis 13; 'families completing the programme will significantly improve their reported healthy family behaviours', hypothesis 14; 'parents reporting the greatest changes in healthy family behaviours will have the most beneficial effect on their child's BMI z-score' and hypothesis 15; 'overweight and obese parents reporting the greatest changes in healthy family behaviours will have the greatest improvements in their own BMI'. The results are shown in table 7.19.

Table 7.19 Healthy Family Behaviours questionnaire results – intervention group only

	0 months Mean (SD) (n=48)	3 months Mean (SD) (n=48)	0-3 month change (n=48)	
			Mean (95% CI)	*p* value
Food and drink	3.53(0.51)	4.04(0.39)	0.51 (0.36 to 0.67)	<0.0005
Exercise	3.19(0.77)	3.68(0.63)	0.49 (0.33 to 0.64)	<0.0005
Family behaviours	3.64(0.68)	3.78(0.58)	0.14 (0.51 to 0.23)	0.003
Positive parenting	3.41(0.52)	3.93(0.51)	0.52 (0.36 to 0.68)	<0.0005

Parents reported a significant improvement in behaviours across all themes ($p < 0.005$). There were no significant correlations seen between parents reporting changes in healthy family behaviours and children's BMI z-score, and improvements in overweight and obese parents BMI and changes in behaviours.

7.4.6.2.2 Y W8? mentor session content evaluation sheet

Evaluation sheets were completed weekly to ensure fidelity to the programme content. The Y W8? mentors used the sheets to record questions from families that required follow- up and content from the weekly sessions that had not been covered and needed to be included in future sessions. Analysis of the evaluation sheets showed 50% of the parent and child sessions were delivered per protocol for all cohorts. The parent and child session during week 4 was only delivered per protocol for 2 out of 5 of the cohorts. Regarding the parents sessions; 22% (2 out of 9) of the sessions were delivered per

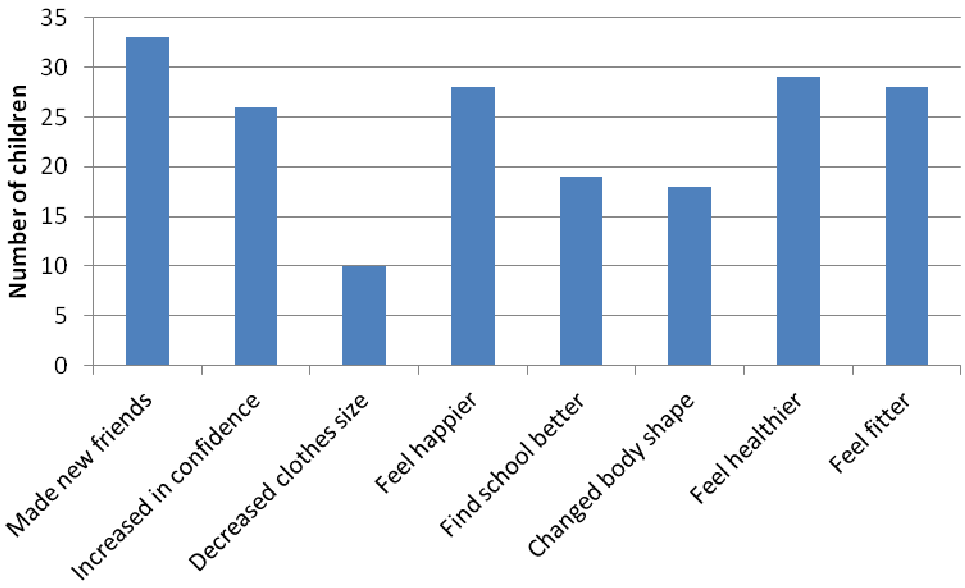
protocol for all five cohorts. The parent workshop in week 3 was only delivered per protocol for 2 out of 5 of the cohorts. All sessions not delivered per protocol were caught up in a future week.

7.4.7 Post-programme evaluation by parents and children – Intervention group only

7.4.7.1 Children's evaluations

This section reports the results of the Y W8? children's user evaluation (appendix 30). All children who completed the programme filled out an evaluation form during their week 12 post-assessment. Figure 7.7 displays the results for the question; 'Since attending Y W8? have you ……..?' Children were prompted to tick as many as were applicable.

Figure 7.7 Results of the question; 'Since attending Y W8? have you .....?'



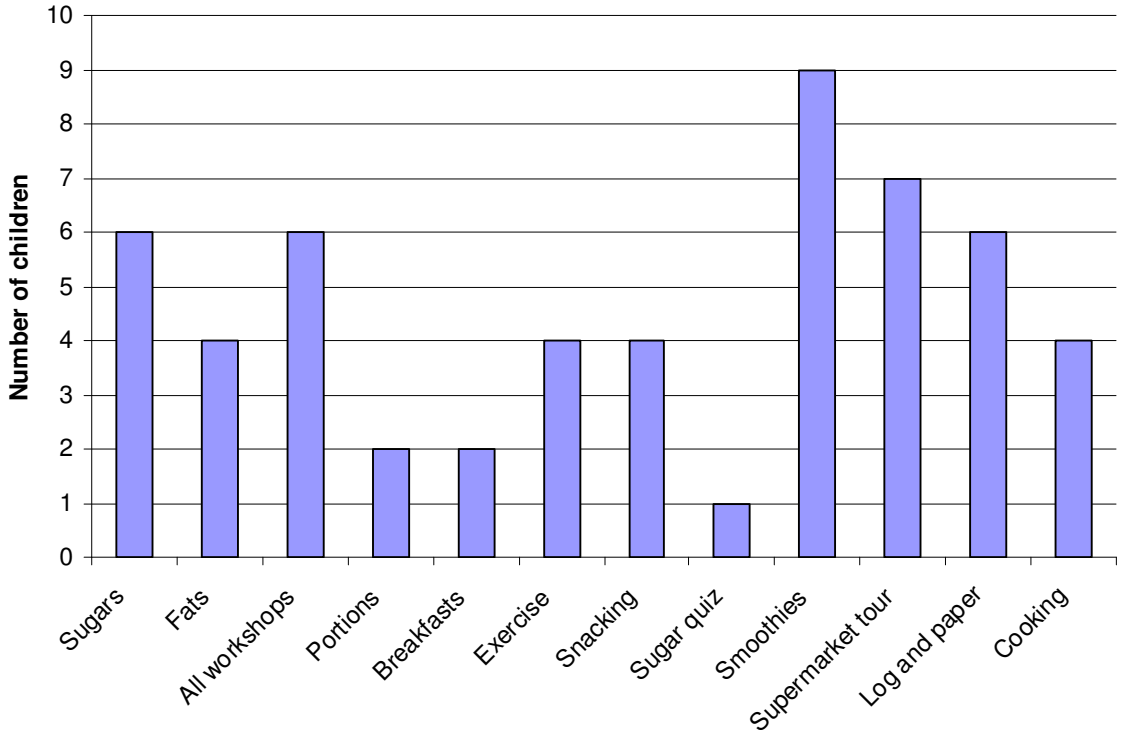
(n=48)

The responses selected the most were; Made new friends (n=33), Feel healthier (n=29), Feel fitter (n=28) and Feel happier (n=28). All children responded to this question with most children (n=36) ticking four or more responses; fourteen children gave four

responses, twelve children gave five responses, eight children gave six responses and two children gave seven responses.

Respondents were asked about the parent and child workshops they attended. Most children rated the workshops very good (69%) or good (21%). Ten percent thought the workshops were fair and no children rated the workshops poor. The children were also asked about the length of the workshop; eighty-three percent thought the workshops were of the right length, with 13% rating them 'Too long' and 4% 'Too short'. Completers were also asked to list which workshops they found the most and least useful. Children were able to list more than one workshop if they wished. The results for the workshops found the most useful are shown in figure 7.8.

Figure 7.8 Workshops children found the most useful

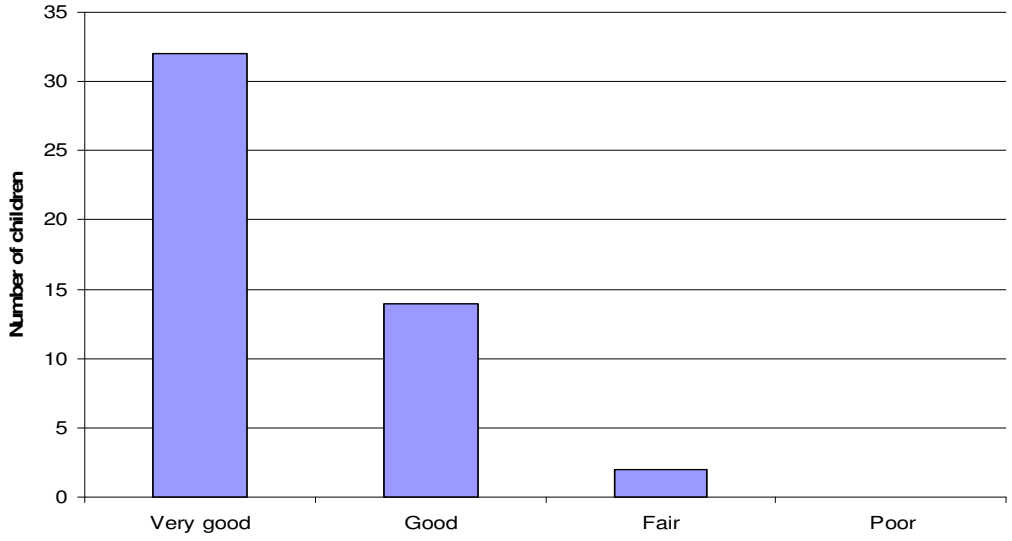


(n=48)

The smoothie session and the visit to the supermarket were rated the most useful. This differs from the feasibility study were respondents rated 'all workshops', 'sugars' and 'fats' as the most useful. Similarly to the feasibility study, few responses were given for the workshops found the least useful, with the smoothie session having two responses and the sugar session one response.

The children's physical activity sessions were highly rated (figure 7.9).

Figure 7.9 Ratings for the children's physical activity sessions

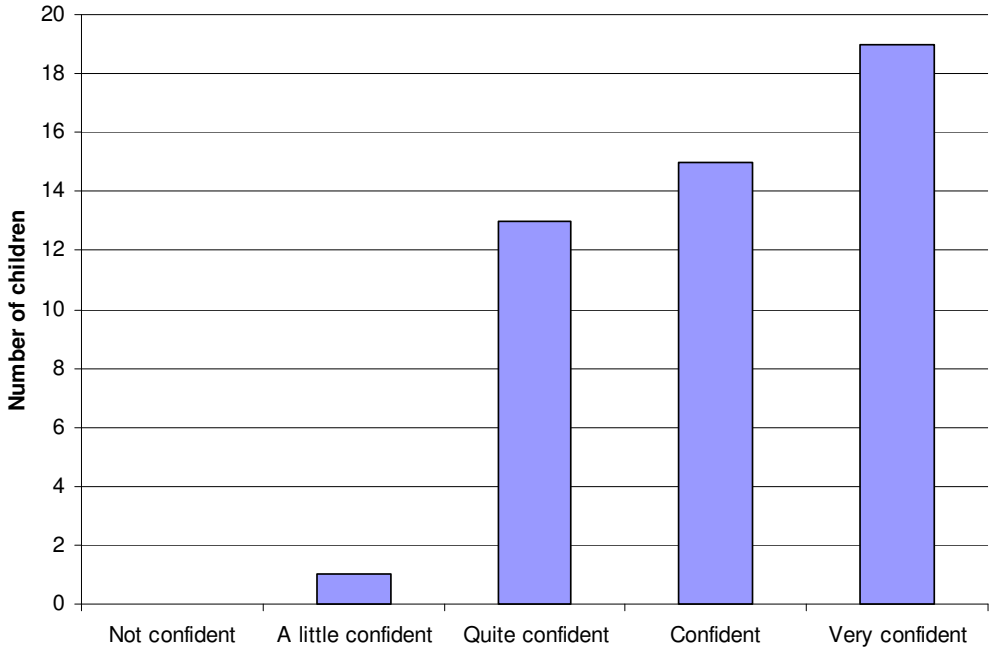


(n=48)

Most children rated the physical activity sessions as either 'Very good' (67%) or 'Good' (29%). Ninety-four percent of children agreed the sessions had increased their confidence and ability to play sports and 85% reported they now had the confidence to try new activities.

Children were asked about their confidence in managing their weight in the future (figure 7.10).

Figure 7.10 Children's confidence in managing their weight in the future



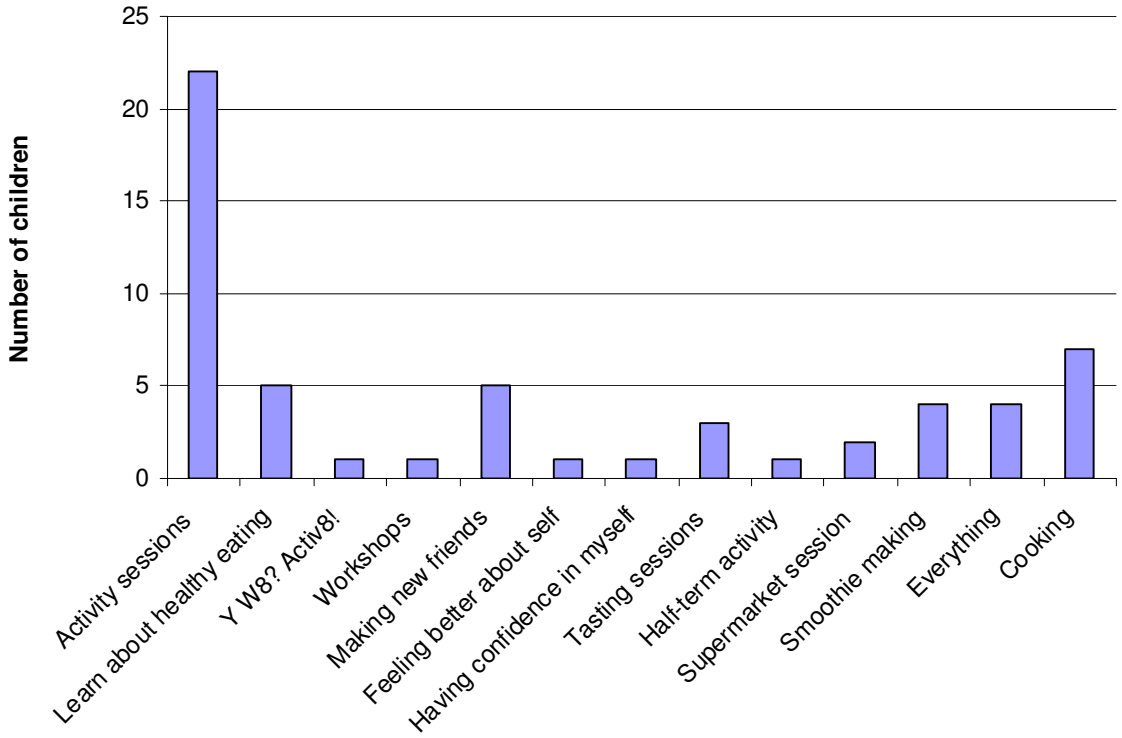
(n=48)

Forty percent of completers felt very confident, 31% confident and 27% quite confident in managing their weight in the future.

Opinion on the 12 week duration of the programme was also assessed with 73% of responders reporting the length was 'Just right', 19% feeling it was 'Too short' and 8% responding it was 'Too long'.

The children were asked 'What were the best things about Y W8?', 'What were the worst things about Y W8?' and 'What other things could have been included to help you more?'. Children were able to list as many answers as were applicable. The results are shown in figure 7.11.

Figure 7.11 Children's responses to 'What were the best things about Y W8?'



(n=48)

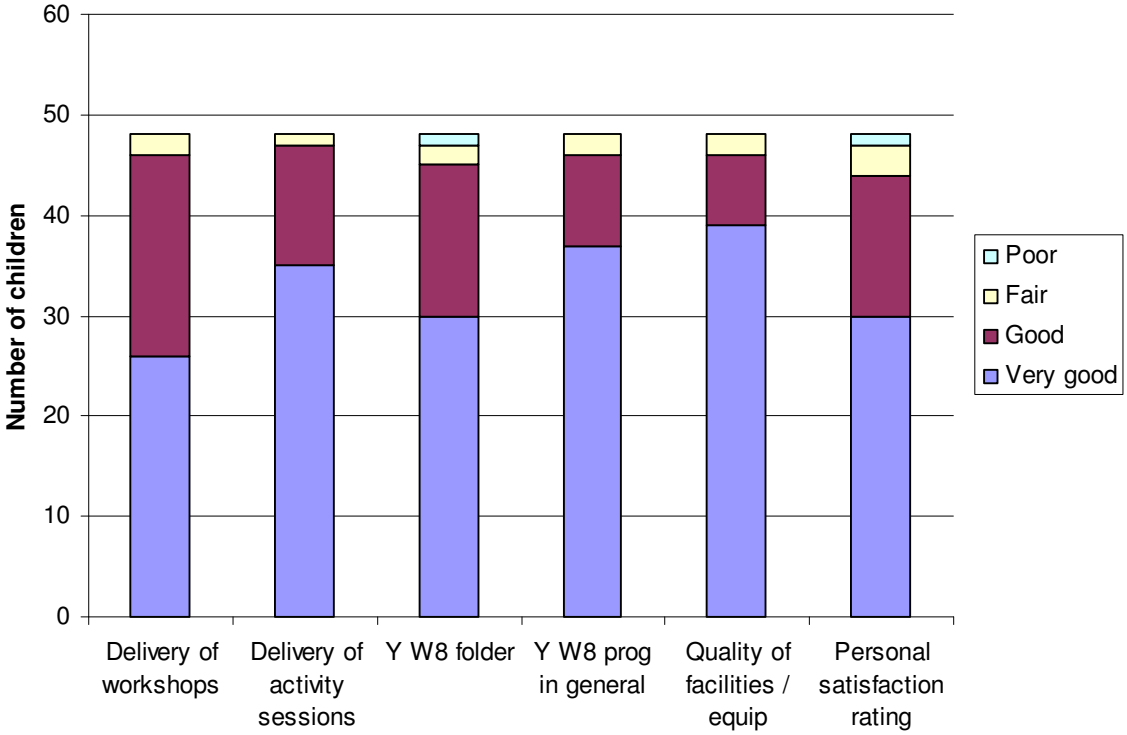
Most children thought the activity sessions were the best thing, with 'Cooking', 'Learning about healthy eating' and 'Making new friends' also popular. Most children (n=40) gave one response to this question, and eight children gave two responses.

There were few responses received for the 'Worst things about Y W8?' with two respondents thinking the workshops were 'too long' and four respondents finding the sessions 'too short'.

There were also only a small number (n=5) responses to the question 'What other things could have been included to help you more?'. Three completers would have liked 'More activities' and two completers 'More cooking'.

Children were also asked to rate the programme and aspects of the programme using the scale; Very good, Good, Fair and Poor. Their responses are shown in figure 7.12.

Figure 7.12 Children's rating of the programme and aspects of the programme

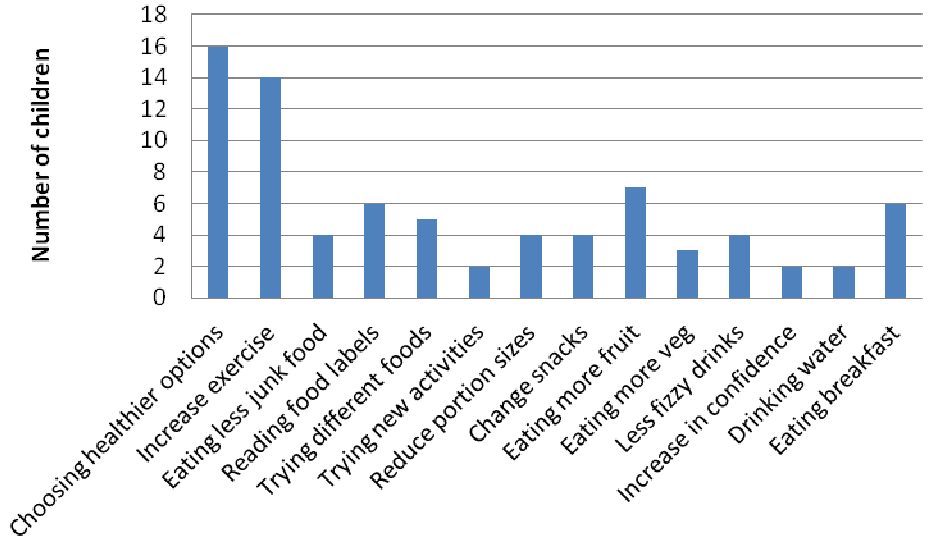


(n=48)

Children rated most aspects of the programme either 'good' or 'very good'. A very small number of children rated the Y W8? folder and their personal satisfaction rating as 'poor'.

Finally the children were asked about the changes they had made since attending Y W8? Children listed numerous changes they had made. These have been themed and are shown in figure 7.13.

Figure 7.13 Children's changes made since attending Y W8?



(n=48)

The most popular answers for the changes they had made were 'choosing healthier options' and 'increase exercise'. Most children (n=37) gave one response to this question, twelve children gave two responses and six children gave three responses.

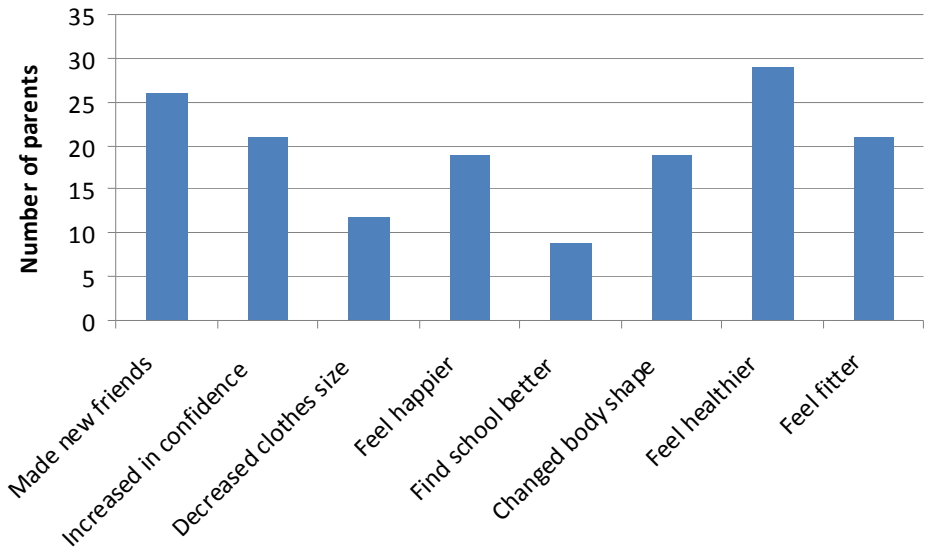
7.4.7.1.1 Summary of children's user evaluation of content, delivery and changes made attributable to the programme

To summarise the children's evaluation of the programme content and delivery and changes they attributed to the programme, during the course of the programme many children made new friends and felt healthier, fitter and happier by the end. Children rated the children and parent workshops and the physical activity sessions highly and most reported an increased confidence and ability to play sports and try new sports. Children found the smoothie workshop and the supermarket tour most useful. Since attending Y W8? 71% felt either confident or very confident in managing their weight in the future. A number of children (19%) thought the programme was 'Too short' and 8% found it 'Too long'.

7.4.7.2 Evaluation of user views by parents'

The results of the Y W8? parent's user evaluation (appendix 31) are reported in this section. All parents who completed the programme completed the evaluation. Firstly, parents were asked to respond to the question; 'Since attending Y W8? do you feel that your child has ……..?'. Parents were prompted to tick as many as were applicable. Figure 7.14 displays the results.

Figure 7.14 Results of the question; 'Since attending Y W8? do you feel that your child has …..?



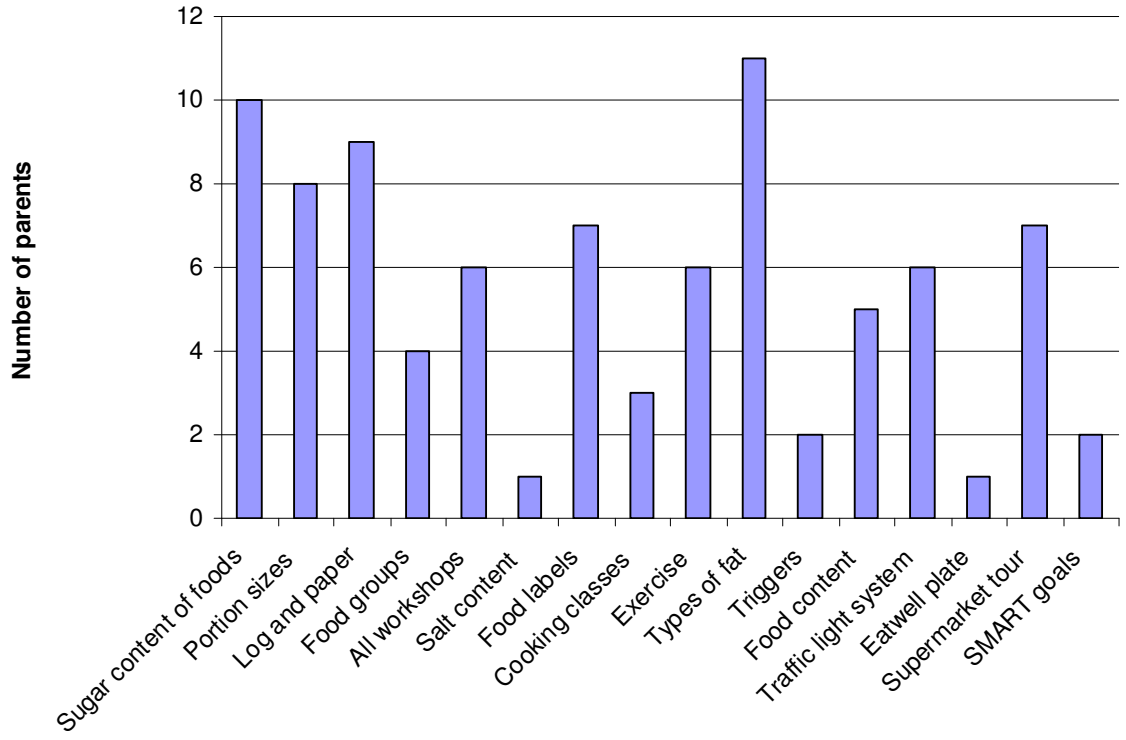
(n=42)

The responses selected the most were; Feel healthier (n=29), Made new friends (n=26), Feel fitter (n=21) and Increased in confidence (n=21). All parents' responded to this question with most parents' (n=32) ticking four or more responses; eleven parents' gave four responses, ten parents gave five responses, seven parents' gave six responses and four parents' gave seven responses.

The Y W8? evaluation then asked respondents about the workshops they attended. Most parents rated the parent and child workshops very good (81%) or good (17%). Seventy-

four percent thought the parent only workshops were very good, 21% thought they were good and 5% rated them fair. The parents were also asked which workshops they found the most and least useful. Parents were able to list more than one workshop. The results for the workshops found the most useful are shown in figure 7.15.

Figure 7.15 Workshops parents found the most useful

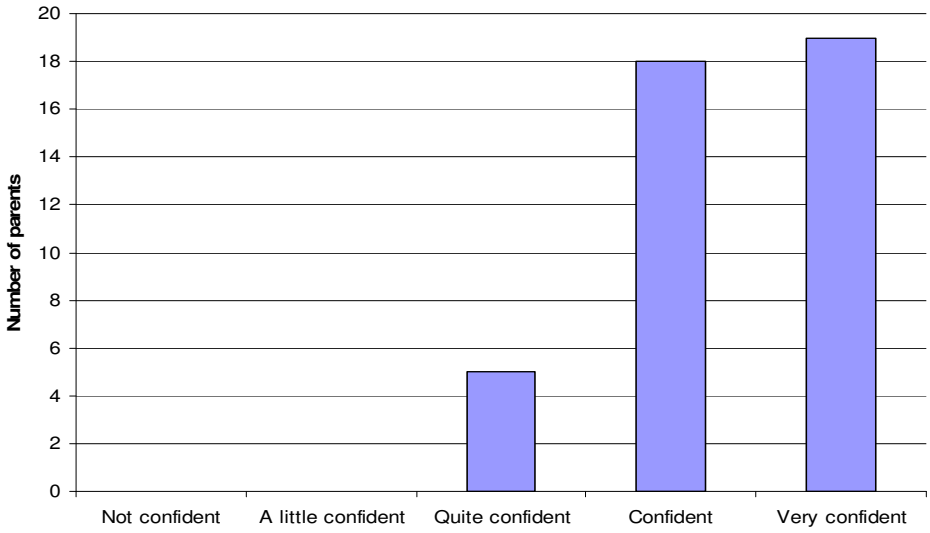


(n=42)

Feedback showed the workshops on fats and sugars, breakfast cereals and portion sizes were rated highly. Few responses were given for the workshops found the least useful, with the 'Balancing act' and 'Problem solving' receiving one response each and one parent commented 'Children at the supermarket as they don't do the shopping'.

Parents were asked about their confidence in managing their child's weight in the future (figure 7.16).

Figure 7.16 Parents' confidence in managing their child's weight in the future

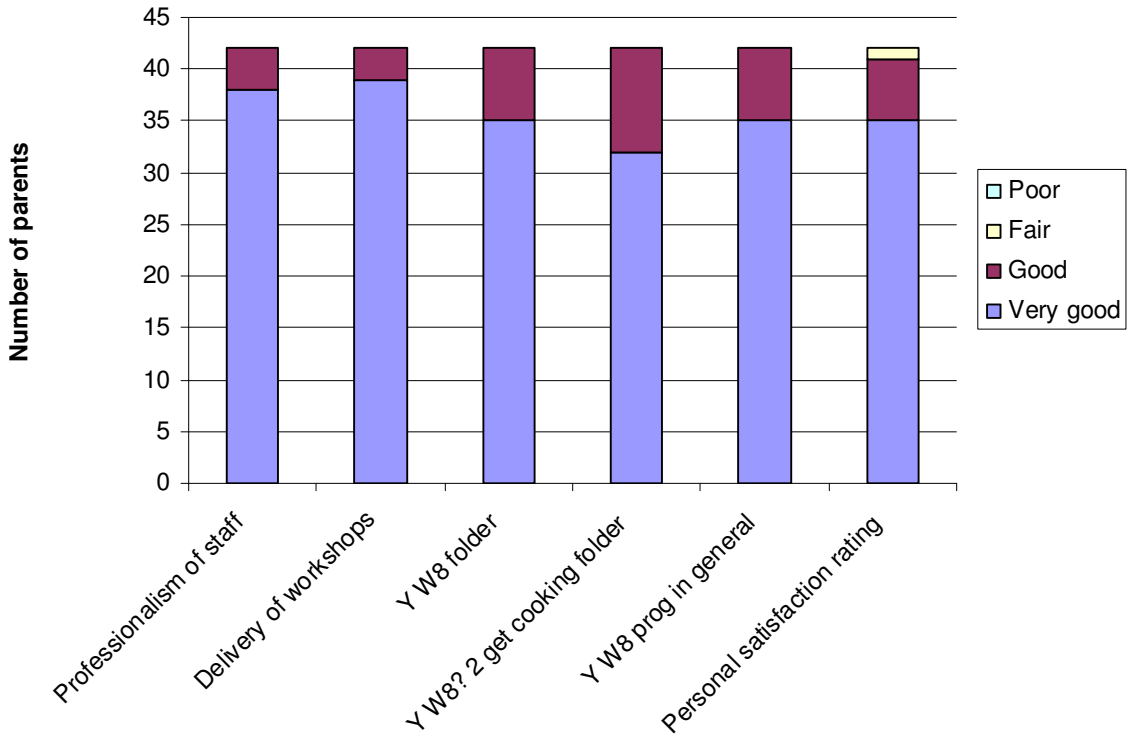


(n=42)

Forty-five percent of parents felt very confident and 43% confident in managing their child's weight in the future. Eighty-three percent of parents reported that completion of Y W8? had enabled other members of the family to make positive changes to achieve a healthier lifestyle.

Parents were also asked to rate the programme and aspects of the programme using the scale; Very good, Good, Fair and Poor. Their responses are shown in figure 7.17.

Figure 7.17 Parents' rating of the programme and aspects of the programme

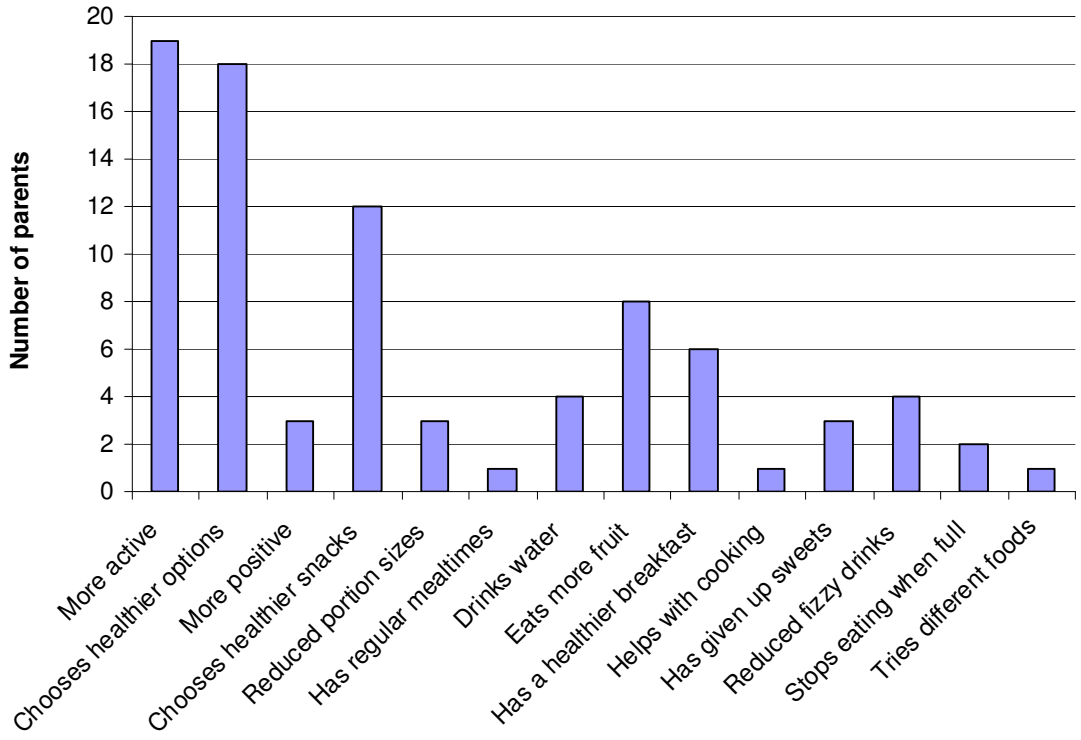


(n=42)

Figure 7.17 shows parents rated all aspects of the programme as 'good' or 'very good', except one parent whose personal satisfaction rating was 'fair'.

Parents documented numerous changes when asked to list the changes their child had made since attending Y W8? These have been themed and are shown in figure 7.18. Parents were also asked to list the changes that had been made for the rest of the family (figure 7.19).

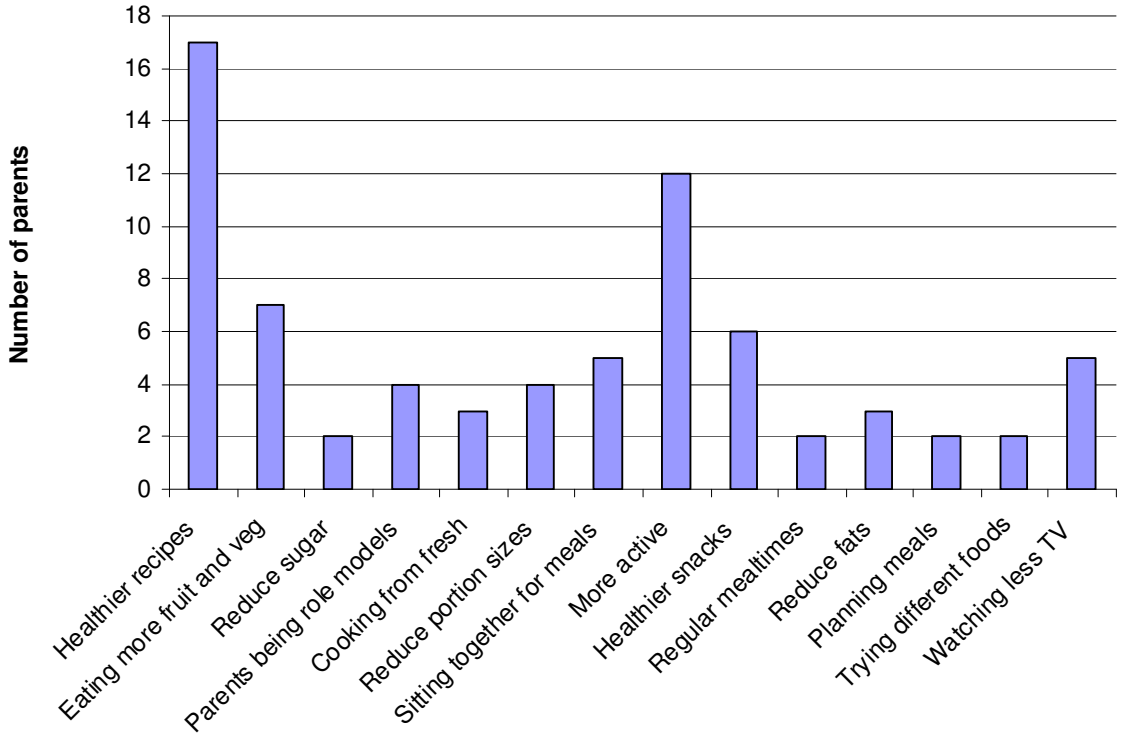
Figure 7.18 Parents responses when asked to list the changes their children had made



(n=42)

The most popular changes the parents felt their children had made were; 'more active', 'chooses healthier options' and 'chooses healthier snacks'. Most parents (n=19) gave two responses to this question, seven parents gave three responses and four parents gave four responses.

Figure 7.19 Parents responses when asked to list the changes that had been made for the rest of the family



(n=42)

Regarding changes for the rest of the family, the most common responses from parents were; 'healthier recipes', 'more active' and 'eating more fruit and veg'. Most parents (n=18) gave two responses to this question, seven parents gave three responses and one parent gave four responses.

7.4.7.2.1 Summary of parents' user evaluation of content, delivery and changes made attributable to the programme

To summarise, the parents who completed the programme reported their children felt healthier, made new friends, felt fitter and increased in confidence since attending. Parents rated both the parent and child workshops and parent-only workshops highly and found then useful, particularly sessions on fats and sugars, breakfast cereals and portion

sizes. A small number of parents highlighted workshops they did not find useful. Since attending Y W8? 88% of parents felt confident or very confident in managing their child's weight in the future and 83% reported that other members of their family had made changes to a healthier lifestyle also. The main changes parents reported for their child were; being more active, choosing healthier options and healthier snacks. No parents reported they, or their child, had not made any changes. For the rest of the family parents reported changes in using healthier recipes, getting more active and eating more fruit and vegetables.

7.4.7.3 Evaluation of data from non-starters / non-completers

Families who did not start the programme (n=4) and those that did not complete the programme (n=7) were followed up to ascertain their reasons for not continuing on the Y W8? programme and to understand if this information could be used to improve the service. Initially families were contacted by telephone and if families did not respond they were sent a feedback form and stamped addressed envelope in the post. (The non-starter and non-completer feedback forms are in appendices 32 and 33). The response rates are similar to the feasibility study with 42% of non-starters and 57% of non-completers in the feasibility study responding, and 50% of non-starters and 57% of non-completers in the RCT responding. Table 7.20 shows the response rate and method for the non-starters and non-completers.

Table 7.20 Response rate and method for non-starters and non-completers

	Total number	Number of responders	Response method
Non-starters	4	2	Telephone (n=2) Postal feedback (n=0)
Non-completers	7	4	Telephone (n=3) Postal feedback (n=1)

Analysis was undertaken to ascertain if those who dropped out of the programme were systematically different from those who completed the programme by comparing the referral method and baseline characteristics; age, ethnicity and BMI z-score (table 7.4). There were no significant differences highlighted.

Most noticeably, none of the families who self-referred dropped out and no families who were referred from the AWMS failed to complete. Of the seven families who were in the intervention group who had come via the NCMP, two families failed to complete the programme. All the other families who dropped out had been referred in by a health professional. This is in line with the findings from the feasibility study and suggests that responding to a poster, flyer or publicity in the media is a measure of motivation towards their commitment to the programme. Families referred in by the AWMS may have had more realistic expectations about being part of a programme such as this.

The results from the telephone and postal feedback showing the reasons for non-starters and non-completers dropping out of the programme are shown in table 7.21.

Table 7.21 Reasons for non-starters and non-completers dropping out of the programme

Number of responders	Telephone feedback	Postal feedback
Non-starters (n=2)	Child refused to attend (n=1) Time was inconvenient (n=1)	
Non-completers (n=4)	Not the right time to attend a programme (n=1) Time was inconvenient (n=1) Childcare problems (n=1)	Child did not enjoy the sessions (n=1)

Although very small numbers make the data difficult to analyse there were a number of contributory factors for those dropping out including it not being the right time for families to start on a behaviour change programme, the time of the day being inconvenient and children refusing to attend or not enjoying the sessions. These results are similar to the feasibility study.

7.5 Discussion

This was an adequately powered RCT, and recruitment has been reported according to CONSORT guidelines (Schulz, Altman and Moher 2010). Recruitment to the study was successful and whilst the control group at pre-assessment was slightly smaller than

recommended by the power calculation this calculation allowed for a 30% drop-out, only 5% actually dropped out. The mean difference of -0.12 used in the power calculation was exactly that achieved by the study, thus this RCT had adequate sample sizes. The change to the recruitment procedures put in place during the feasibility study e.g. enabling GPs to refer electronically and improved use of posters and the media, assisted with recruitment of families.

There is a general agreement in the literature that there is a lack of evidence from well conducted RCTs on the treatment of childhood obesity (NICE 2006, SIGN 2003, Oude Luttikhuis et al. 2009). This RCT offers evidence to support the use of family-based treatment programmes in the treatment of childhood obesity and displays positive results in the short-term. Results from the RCT showed a significant change in BMI z-score between the control group and the intervention group ($p < 0.0005$) over the 12 week period. For the intervention group 81% of children completed the programme. There was a significant positive effect on child BMI z-score and parent BMI in the short-term (3 months). The magnitude of the change in BMI z-score achieved was very similar to the results achieved in the feasibility study. Analysis showed this positive effect on weight status did not adversely affect linear growth; height increased significantly and height expressed as a z-score did not change significantly. Results for the parents change in BMI were greater than that achieved in the feasibility study.

The clinically significant reduction of 0.5 BMI z-score suggested by Reinehr and Andler (2004) was not achieved by any children, regardless of their randomised group, by the end of the 12 weeks. However, 88% of the intervention group reduced their BMI z-score, (80% by less than 0.25 units and 8% between 0.25 and 0.5 units). The children's results were also explored by recording whether any moved between the obese, overweight and 'normal' category. In the intervention group seven children changed category over the 12 weeks; one child moved from the obese to overweight category and six from being overweight to 'normal' weight.

Children and parents user evaluations demonstrated how the families found the programme enjoyable and useful. Similarly to the feasibility study children reported making new friends, feeling healthier, fitter and happier. Ninety percent rated the

workshops very good or good with the most useful sessions being making smoothies, the supermarket tour, sugars and log and paper. Parents also rated both the family workshops and parent only workshop highly and found the fats, sugar and portion sizes workshops the most useful. Ninety-four percent of the children reported increased confidence and ability to play sports, and 85% reported the confidence to try new activities. Both the children on the intervention group of the RCT and those in the feasibility study thought the best thing about Y W8? were the physical activity sessions. Seventy-one percent of children and 88% of parents felt confident or very confident in managing their or their child's weight in the future, and most parents reported that other members of their family had made changes to healthier lifestyle also.

The final aim was to carry out further testing of a number of hypotheses related to improving health behaviours and health status. The results of the secondary outcomes for the intervention group only were used for this analysis. Children's self-esteem improved significantly over the duration of the programme. A medium-sized positive correlation was found between change in BMI z-score with change in physical appearance, with increases associated with improvements in BMI z-score. Children and parents significantly increased their score of how important physical activity was to them. Both children and parents on average significantly increased the number of days they achieved the recommended level of activity, and the number of days a week they took part in activity at an increased intensity. The amount of fruit and vegetables children consumed also increased significantly on average. The Healthy Family Behaviours questionnaire was used to gain further insight into the participants eating and activity behaviour. A significant improvement was reported across all themes; food and drink, exercise, family behaviours and positive parenting.

This study has reported the implementation of the RCT of the 'Y W8?' childhood obesity treatment programme within a routine service context. Results have shown the intervention is effective when compared to a waiting list control group. Children and parents post-programme evaluations showed the programme was highly rated and families reported making changes for both the child attending the programme and the rest of the family. In the next chapter these results are compared with the outcomes of the other similar UK based RCTs which have been discussed previously in chapter 4.

Chapter 8 Discussion and interpretation of results

8.1 Introduction

This chapter describes the strengths and limitations of the methodology used to develop the intervention and the two studies detailed in this thesis. The implications of the findings are also discussed and suggestions for possible future research are given. The results of the intervention are compared with other RCTs including an analysis of the cost per participant to deliver a programme such as this. A critique is provided of the evaluation design and measures. The implications for practice are reflected upon and the sustainability of the intervention in the current organisation, and other UK organisations is considered by exploring the Normalisation Process Theory (NPT) framework. Finally, suggestions are made for improvements to the programme based on feedback from families and the Y W8? mentors delivering the programme.

8.2 Critique of the development of the intervention

8.2.1 The Intervention Mapping (IM) methodology

The Y W8? programme was developed using a structured, evidence-based approach as recommended for obesity management within current UK Government policy (SIGN 2010, NICE 2006). The IM protocol provided a method of systematic development as programme developers are required to work their way through the protocol gathering evidence and selecting theory-based intervention methods to be included in the final programme. Previous authors have noted that interventions are commonly designed without evidence of having gone through a process of matching the intervention features to the behavioural target, the target population and the context in which the intervention will be delivered (Michie, van Stralen and West 2011). As previously stated, using the IM protocol was a strength of this research as it ensured theories, evidence and user views were integrated and developed into an intervention to be delivered to local families. The protocol helps to bridge the gap between evidence, theory and policy and enables researchers to transform available knowledge into practical interventions that can be evaluated and their results shared. In particular, in this study following the protocol led to

the steering group being convened. The group was chaired by the researcher and comprised local health professionals, council employees and a representative from education. The formation of this inter-disciplinary group brought together a vast amount of knowledge and experience which combined to ensure the programme was developed to support the needs of the local population and make use of local community assets and strengths. Although the group could not bring money to support the programme their time, knowledge and support through 'in-kind funding' such as reduced rates for facilities, and time to attend sessions to quality control the content being delivered, meant the programme could be delivered using a small budget. This benefit has also given long-term gain as the 'in-kind funding' has been honoured throughout the duration of the programme and ensures that whilst NHS funds are being reduced the programme can continue to run at full capacity.

A common criticism of the IM approach is how time consuming it is which also affects the budget required, the staff time needed to complete the process, and the time it takes to begin delivery of the programme and embed it in routine service. This criticism was true for this intervention also. Despite this, for this intervention, the full version of the IM protocol was used to ensure all steps were completed correctly and the maximum amount of information was gathered to influence intervention development. It also ensured the developer produced thorough documentation of the effective methods and successful strategies, which would improve fidelity and the likelihood of sustainability. Assurance was given from funders that they supported the process and accepted the time scales for development. To improve the IM protocol, and reduce the time required for the process, the number of matrices of change objectives created in step 2 could be reduced, especially when the focus is on a complex health condition. As in this intervention, the number and complexity of the matrices can be daunting and create numerous performance objectives which are difficult to manage within an intervention. Programme developers could reduce the number of matrices by choosing to focus on a small number of health behaviours or use theories to direct their choice of objectives. Some authors have reported using a shortened version (Verbestel et al. 2011 and Singh et al. 2006), with Verbestel et al. (2011) choosing to guide the specification of their performance objectives according to self-regulation theory and implementation theory.

8.2.2 Taxonomy of behaviour change techniques

The BCTs used in the intervention were classified using the CALO-RE taxonomy (Abraham and Michie 2008). Craig et al. (2008) suggest that the most challenging part of evaluating a complex intervention is defining the actual intervention, and the number of components and range of effects can vary widely. It can be difficult to identify the effective elements in multi-component interventions and a good theoretical understanding is needed of how the intervention causes change. Therefore, utilising the taxonomy was a strength of this research enabling clear, precise reporting of the programme and enhancing the possibility of identifying the effective ingredients within the intervention (Michie et al. 2009b). The CONSORT statement (Schulz, Altman and Moher 2010) requires authors to explain the intervention thoroughly so it may be replicated if required. Using the CALO-RE taxonomy for an intervention such as the Y W8? programme assists with this as each component can be identified and recorded during which stage of the intervention it is delivered.

8.3 Critique of the implementation of the intervention

8.3.1 Study power and reporting

In comparison with other studies which were underpowered (Bryant et al. 2011, Coppins et al. 2011, Golley et al. 2007), or when power was not reported (Kalavainen, Korppi and Nuutinen 2007, Kalavainen, Korppi and Nuutinen 2011, Croker et al. 2011), the RCT in this study had sufficient power to show the primary outcome of expected change in BMI z-score of -0.12 at 12 weeks post-baseline. Data concerning all those eligible was kept and a participant flow-chart is show in figure 7.3. The reporting of the recruitment to the RCT also followed the CONSORT guidelines for reporting trial methods and outcomes (Schulz, Altman and Moher 2010). In the RCT, as well as the feasibility study, the data collection and evaluation was in line with the SEF for weight management interventions (Roberts, Cavill and Rutter 2009).

8.3.2 Programme fidelity

A further strength worth noting is programme fidelity. Michie et al. (2009b) recommended that as part of the detailed description of an intervention the fidelity to delivery protocols should be described. Using a manual is a suggested way of improving fidelity, and a manual was produced of the Y W8? programme during step 5 of the IM protocol (appendix 44 documents an example week from the manual. The full manual is available from the author on request). Fidelity of interventions is generally poor. Borelli et al. (2005) assessed 287 evaluations of behaviour change interventions and found only 27% carried out an assessment of fidelity. Experts in the field suggest intervention fidelity should become an integral part of the conduct and evaluation of all intervention research (ICEBeRG 2006). The 'gold standard' to assess fidelity is to audiotape or video tape the session and record the errors of omission. This method would not have been practical for this study due to the resources required. Other acceptable methods include external observers, self-report by those delivering the intervention and participant report (Michie 2007). In this study consistency of delivery was promoted by ensuring after each session the Y W8? mentor completed a session evaluation sheet and kept it with the session notes. Any content that was not covered was recorded and followed up in future weeks and a record was kept of when this happened. Any questions from families that needed to be followed up at a future session were also recorded and marked when they had been addressed. Y W8? mentors were required to review the evaluation sheets weekly to ensure that by the final group session all the content had been covered correctly, and all questions had been answered. In addition, the family workshop delivered in week 10 and the parent workshop in week 11 were designed to recap the content that had been covered in previous workshops and gave families time to consolidate the learning and refresh their understanding if necessary. Also, Y W8? mentors followed up families weekly with telephone calls to check their understanding of the weekly sessions, confirm their attendance at the following session and offer more support if necessary.

During the feasibility study (chapter 6) data was recorded regarding which sessions were required to be amended. A more rigorous process was carried out during the RCT (chapter 7), and analysis shows 50% of the twelve parent and child sessions were delivered per protocol for all groups, and overall 91% of sessions were delivered as

planned. For the nine parents' sessions, 2 of the 9 sessions (22%) were delivered per protocol for all groups, and overall 85% of sessions were delivered as planned. Reasons for not being able to adhere to the protocol included the number of questions being asked by participants, extra time needing to be given for those for whom English is not their first language and behavioural issues with some children. This data compares favourably with other reported behaviour change interventions. Harting et al. (2004) published the results of a CVD counselling study and reported 66% of the intervention was delivered per protocol, and Davis et al. (2000) reported 50% of their nutrition education intervention was delivered as planned.

8.3.3 Blinding

A limitation of the methodology employed in the RCT was the lack of blinding of the researcher to the group allocation. Therefore, the researcher knew which families were in which group, which could have resulted in bias. This might include inadvertent encouragement to families in the intervention group to give favourable answers at their post-intervention assessment. However, due to the very small team delivering the programme, the researcher and one other member of staff, who were responsible for all data collection and delivery of the intervention it was not possible to keep them blinded to the group allocation. A paper providing an extension to the CONSORT statement (Zwarenstein et al. 2008) presents additional guidance on eight items in the original CONSORT text. They suggest if blinding was not done, or was not possible, this should be explained. The authors accept that in pragmatic trials blinding may be impossible but state, 'it is still desirable and often possible to blind the assessor or obtain an objective source of data for evaluation of outcomes' (Zwarenstein et al. 2008). However, Wood et al. (2008) concluded that the results of unblinded RCTs tended to be biased toward beneficial effects only if the RCTs outcomes were subjective as opposed to objective. In this instance, the primary outcome measure of the RCT was BMI z-score which is an objective measure, so the lack of blinding is not a threat to the conclusions that have been drawn in this study.

8.3.4 Programme delivery

It is possible that only having two team members delivering the intervention could have been a constraint as their own level of motivation and enthusiasm could have been a limiting factor in the outcomes. As this author was one of the Y W8? mentors and worked closely with the other mentor, and both were very experienced in delivering weight management programmes, this limitation is not considered a key factor for either study. Indeed, an advantage of just having two Y W8? mentors is it reduces the variation between programme deliverers. Additionally, funding was not available to employ more workers than this so the programme was delivered making the best use of the resources and funding that were available.

8.3.5 Parental attendance

Although both parents were invited to attend the programme, (when the family situation was appropriate for this), 93% of the parents in the feasibility study and 91% who attended the RCT were mothers. The recruitment of fathers to voluntary parenting programmes can be difficult (Bayley, Wallace and Choudhry 2009), and this has been demonstrated in other childhood obesity treatment programmes. For example, WATCH IT (Bryant et al. 2011) reported 89% of parents in the intervention group and 97% of parents in the control group were mothers. To achieve lifestyle changes for the family it would be preferable if both parents could attend as they are needed to work together. The National Service Framework for children (Department of Health, Department for Education and Skills 2004) emphasises the need to engage fathers in parenting programmes and suggests not having the father there may weaken the efforts of interventions requiring parents and children to work together. To improve the recruitment of father's interventions would need to address the barriers preventing their attendance and change perceptions of fathers who view programmes to be focussed on the mother. However, this will take time, finances and may require further staff training. For example, money would need to be made available for a crèche or childcare for siblings unable to attend the programme (Department for Education and Skills 2004), marketing materials would require redesigning using images reflecting father involvement and the programme content and delivery methods might require adjusting (Bayley, Wallace and Choudhry 2009).

8.4 Critique of the evaluation of the intervention

8.4.1 Evaluation approach

The main strength of the feasibility study is that it used a mixed-methods evaluation approach. This enabled a detailed process and outcome evaluation to take place to gain evidence of the beneficial effects of the programme on child and parental health status, and the acceptability of the programme to families. The data collection and evaluation was comprehensive and was largely consistent with the SEF for weight management interventions (Roberts, Cavill and Rutter 2009). The quantitative data incorporated a wide range of outcome measures, including child and parental measures of weight and height to enable BMI to be calculated, measures of self-esteem, family behaviours and a dietary assessment. The qualitative methods gathered from the user evaluations and interviews with parents were used to support this and 'illustrate' (Bryman 2006) the findings from the quantitative data. It also provided evidence of the parent's views of the programme and how it could be improved. Just using the quantitative data would have given an indication of the effectiveness of the intervention and just the qualitative data would have provided families feelings towards, and satisfaction with, the intervention. The combination of the two allowed a judgment to be made regarding whether the study should continue to a RCT, and gave the researcher evidence regarding changes that needed to be made to the operational aspects of the programme.

However, the use of qualitative data did lead to a number of limitations. There were only a small number of interviews that were undertaken to gain further information regarding the acceptability of the programme. The six interviews that were completed provided a large amount of rich data; however, it is uncertain whether saturation was reached in all of the areas discussed, therefore caution needs to be used in interpreting the results. Due to this, the information gleaned from the parents is used in the form of illustrative quotes to support the outcome evaluation measures and should be read as an indication of how parents felt.

The inexperience of the researcher in qualitative research is worth exploring further. The researcher was skilled in many of the techniques used for qualitative interviewing such as use of open questions, active listening skills and summarisation (Hunt and Pearson 2001, Rollnick, Mason and Butler 1999). Initial interviews took under an hour to conduct while later ones took up to an hour and a half, an indication of conducting fuller more in-depth interviews, suggesting that with practice the researcher become better at facilitating the interviews and less directive. Using the researcher, who delivered some of the programmes, as interviewer may have introduced bias in both the interviewing and analysing process. However, this could also be viewed as an advantage. The researcher was fully immersed in the programme and understood why it was designed in the way it was. Having this person conduct the interviews could have resulted in more in-depth interviews being conducted and further exploration of pertinent points (Rollnick et al. 2005).

During the interviews parents were asked about their concerns, issues and ideas of how the programme could be run better. As the interviews were conducted by the researcher it might have been difficult for some parents to answer honestly in the interview situation. This social desirability bias (Nederhof 1985) was mitigated in a number of ways. First by acknowledging the possibility and ensuring continuing support and supervision from the supervision team. Secondly, the qualitative results have been used to support the quantitative outcome evaluation measures rather than being used as a measure of change in its own right.

A limitation of the qualitative research is that no children were interviewed to gain their thoughts and feelings on the programme. Further interviews were not undertaken due to time constraints and funding not being available to conduct and analyse them. At the time, the emphasis needed to be placed on implementation of the programme, embedding it in routine service and evaluating it using objective measures. Interviews, or focus groups, with children would have added to this body of work. Children were given the opportunity to provide more information about the programme in their post-programme evaluation forms and these comments have been used in the analysis (section 6.4.6.4.2). Therefore, the fact that the children were not interviewed does not in itself detract from the conclusions made overall.

It would also have been insightful to conduct in-depth interviews with families who chose not to start, (non-starters), or did not complete, (non-completers), the intervention. However, it is notoriously difficult to engage such participants in research so it was decided to contact these families by telephone or, if families did not respond, by letter, and to offer a feedback form. Using these methods the number of responders was reasonable, (43% of non-starters and 58% of non-completers), and information regarding why they were no longer attending the programme was gathered. Attempting to collect this information was a strength of this research as the information gathered was useful for planning future programmes.

Using a mixed-methods evaluation approach this study was able to capture a large amount of comprehensive information through a variety of methods. The researcher tried to use the funding available to gather a thorough data set that would allow insight into the effectiveness of the programme. Interviews with parents at a later follow-up time point would also have been useful but were not able to be completed with the finite resources available. For example, at the 9 month post-baseline follow-up appointment (for measurement of BMI), some parents talked about how they were finding it difficult to sustain the changes they had made and that refresher sessions of Y W8? would have been useful. These comments were not recorded. An interview to explore the potential barriers to maintaining the changes would have provided useful additional data to plan programme modification for the future. Future research should address this by completing a qualitative evaluation at each of the time points where height and weight are recorded. This research would be useful to explore the barriers families face in sustaining behaviour change and how they can be supported better in the longer-term to sustain, or improve, the positive changes they have made to their lifestyles.

8.4.2 Intention-to-treat analysis

A strength of the evaluation of both studies is that intention-to-treat analyses was employed when evaluating the 9 months post-baseline follow-up data in the feasibility study and the 12 week post-baseline data in the RCT. This is important both for reporting the effects of the intervention and being able to make an honest comparison of the results

with similar studies. Less than half of the interventions in the Cochrane systematic review used intention-to-treat analysis (Oude Luttikhuis et al. 2009), and the review points out that 'many of the studies dealt with high dropout rates' (p.1588). It is possible that those who have had a successful outcome are more likely to attend for follow-up appointments so failure to report an intention-to-treat analysis is likely to overestimate the benefits of the intervention. Also, comparisons between results from interventions needs to be carried out on a like-for-like basis only, as results from interventions that have used an intention-to-treat analysis may well report being less effective than those who have not accounted for missing data.

8.4.3 Follow-up of families

With hindsight a further follow-up review for both the feasibility study and RCT would have proven valuable but was not achievable due to the small team, lack of funding and other priorities in the workplace. Collecting data up to 12 months post-baseline would have ensured that the 'before-and-after' data collection occurred at the same time of the year as seasonal variations impact on physical activity (Riddoch et al. 2007) and on weight gain (Gillis, McDowell and Bar-Or 2005). Furthermore, both 6 and 12 months post-baseline follow-ups would permit better comparison with other obesity treatment interventions reported in the Cochrane review (Oude Luttikhuis et al. 2009).

Regarding the RCT, follow-up data beyond the 12 weeks of the intervention, ideally up to 12 months, would have enabled comparison of the longer-term effects of the programme compared to a control group. It would have also allowed comparisons to be made between this intervention and other UK based childhood obesity treatment RCTs (Bryant et al. 2011, Coppins et al. 2011, Croker et al. 2011, Hughes et al. 2008, Sacher et al. 2010). However, the PCT hosting and funding the study regarded 9 months too long to wait for the programme when the resources were available to deliver the intervention to families. Therefore, the families were asked to wait 12 weeks when in the control group and then offered the next available intervention. In the most recent systematic reviews of childhood obesity treatment programmes both Sung-Chan et al. (2012) and Ho et al. (2012) highlighted the need to conduct follow-up measurements to assess long-term

effectiveness of programmes. This is a consideration for funders to ensure budget is available for this and for researchers to include this in research protocols.

To assist with the well-recognised problem of getting longer-term follow-up, and other common problems such as recruitment, Relton et al. (2010) suggest the use of the 'cohort multiple randomised controlled trial' design. This new approach for pragmatic RCTs has a number of key features; recruitment of a large observational cohort, regular measurement of outcomes for the whole cohort and provision for multiple RCTs over time. Within each RCT eligible individuals can be identified and some of them randomly selected for the intervention. Comparisons can then be made between the outcomes of the randomly selected individuals compared with the eligible individuals who have not been selected. This design has a number of advantages; the capacity for multiple RCTs, ease of obtaining long term outcomes, ongoing data regarding normal changes in the population and to routine treatment, and a large number of recruits to increase the statistical power of the study. Within the field of childhood obesity there is potential for this design as the NCMP data could be used as the recruitment method for the large observational cohort, and the results could be used for selection of individuals for interventions. However, to be able to use this design more frequent measurements would be need to be taken, (not just in reception year and year 6), to ensure a useful data set to measure the change in outcomes and selection of individuals for interventions. In addition, the measurements would need to be taken for a longer duration, perhaps up to the time the child leaves school in year 11, to provide long term outcomes.

8.4.4 Economic evaluation

A full economic evaluation of the intervention would have proven valuable in analysing cost-effectiveness and calculating the likely cost should the programme be expanded. Both the NICE guidance (NICE 2006) and the Cochrane review (Oude Luttikhuis et al. 2009) point to the paucity of evidence on the cost-effectiveness of non-pharmacological interventions for the treatment of obesity. Interventions such as Y W8? normally have a low reach because groups can only enrol about 12 families at any one time. The programme would need to be scaled up considerably if reach was to increase so an

analysis of cost-effectiveness would be crucial in any decision making regarding this. Hollingworth et al. (2012) used economic data available from RCTs conducted in the UK NHS to treat childhood obesity to estimate lifetime cost effectiveness of lifestyle interventions. They used the National Heart Forum 'obesity model' to predict changes in life expectancy and incidence of weight-related diseases over a lifetime. They estimate that an intervention causing a reduction of -0.13 BMI z-score (median effect size) and costing £400 per family (moderate cost) will lead to an increase of 0.19 life years in the life expectancy of obese 10-11 year olds. The cost of the intervention will not be paid back until approximately 58 years post-intervention. However, this model takes no account of the small but measureable effects on parents' outcomes that family interventions may have.

Focusing on the UK based RCTs described in chapter 4 only Coppins et al. (2011) described information regarding cost. They estimate the cost per child to take part in their project was £403. The authors emphasised the considerable funding that would be required to enable their programme to be rolled out. The West Midlands regional evaluation of weight management programmes for children and families (Upton et al. 2009) carried out an economic evaluation assessing the costs of implementing the interventions and calculating the cost per participant. Costs gathered from the regional programmes included staff training, salaries, purchasing of materials, etc. The evaluation used data from 1st July 2007 to 1st July 2009 from projects being delivered in the region. The estimated costs reported in the regional evaluation are shown in table 8.1. It is worth noting that these estimated costs are based on full recruitment and the authors note that the costs will have been considerably higher for programmes which had difficulty recruiting (Upton et al. 2009). The MEND and WATCH-IT programmes described in table 8.1 refer to the programmes being delivered in the region between July 2007 and July 2009. These are not the same studies described in section 4.4 and section 8.5.

Table 8.1 Estimated cost per participant for the projects included in the West Midlands regional evaluation

Project	Estimated cost per participant
Fun4life	£300
Fitter Families	£396 - £423
GOALS	£500 - £600
MEND	£510
One Body One Life	£236
WATCH-IT	£669
Y W8?	£203

(Upton et al. 2009)

The cost estimates provided in the regional evaluation and the Coppins et al. (2011) study suggest that Y W8? is a low-priced intervention when compared with the other projects. A contributing factor to keeping costs low could be linked back to the use of the IM protocol and the necessity to involve local partners and the analysis of local community capacity and resources that took place in step 1. During this step local partners offered low-cost resources and discounted the use of facilities to assist in the delivery of the programme. This commitment from local partners was achieved by using the IM methodology and has led to a low-priced, effective intervention being developed and implemented.

8.4.5 Studying the context of the intervention

A limitation of the evaluation of the study is that an evaluation was not carried out to understand how the intervention interacts with the context to produce the outcomes. The evaluation design was built on realist principles (Pawson and Tilley 1997), as during development different stakeholders were consulted with to gain their understanding of how the programme might work, the intervention was implemented within the context of the NHS and there was a focus on BCTs and outcomes. To further understand the context of the intervention interviews could have been conducted with stakeholders such as PCT

funders, referrers, programme deliverers and local health professionals to gain an understanding of their views of how the programme has been implemented in the local area, the context in which the programme operates and their understanding of how the programme works. This would have gained further understanding of the programme including the social, economic and organisational context. The information would also have helped with planning for sustainability and spread.

8.5 Limitations of the measures used in the studies

Measuring change in children's and parents' weight status and healthy lifestyle behaviours was key to measuring the effectiveness of this intervention. In addition, the results were shared with the families so they could reflect on the changes they had made and hopefully enable them to self-manage in the future. The measures chosen for this study were selected for their practical application with the age group and appropriateness for the level of intervention being undertaken. The main measure of BMI converted to BMI z-score has already been discussed in sections 3.2.1 and 3.3 respectively. This measure is now widely used in the literature and provides a means of comparing the results of different interventions.

Analysis of the literature pertinent to this research showed numerous tools were being used to capture information regarding children and families dietary and physical activity behaviour. When this intervention first commenced there was little information available from other UK programmes regarding the tools they were using to capture behaviour change data. Hence, the researcher chose the tools that were appropriate and provided a balance between obtaining valuable information which could be used to assess the effectiveness of the programme and be fed back to the participants, without placing too much burden on the families. The number of UK based interventions has increased and it is now possible to make comparisons between the effectiveness of these programmes when focusing on change in BMI z-score as the measure. However, the number and variety of measures used makes it difficult to make direct comparisons on the effect of these interventions on changes in other health outcomes such as eating and exercise behaviours and self-esteem. Table 8.2 displays the tools used by the UK based RCTs analysed in section 4.4 and demonstrates the number of different measures used in these

childhood obesity treatment programmes. Upton et al. (2009) suggested in the West Midlands regional evaluation that 'changes in behaviour related to food intake and exercise should also be measured in a systematic and standardised way' (p. 4). Recommendations in the NICE guidance or SEF regarding the tools to use would be helpful to encourage programmes to use the same measures and thereby allow direct comparisons to be made.

Table 8.2 Tools used by UK based childhood obesity treatment RCTs to measure health outcomes

Intervention	Anthropometric measures	Physical activity measures	Dietary measures	Self-esteem measures
Y W8?	BMI z-score	Amended HSE questionnaire	3 day food diary	Amended SPPC (Harter 1985)
SCOTT (Hughes et al. 2008)	BMI z-score	Accelerometer	None reported	PedsQL (Varni et al. 2003)
MEND (Sacher et al. 2010)	BMI z-score Waist circumference Body fat	Fitness (step test) Locally developed questionnaire	None reported	SPPC (Harter 1985)
WATCH IT (Bryant et al. 2011)	BMI z-score Waist circumference Body fat	Fitness (step test) Accelerometer PAC-Q (Kowalski, Crocker and Faulkner 1997) Robinson School-based Sedentary Behaviour Questionnaire (Robinson 1999)	Locally developed Watch It Diet questionnaire Locally developed Home Food Availability Checklist DEBQ (Dutch Eating Behaviour Questionnaire) (VanStrien et al. 1986)	PedsQL (Varni et al. 2003) Strengths and Difficulties Questionnaire (SDQ) (Goodman 1997) SPPC (Harter 1985)
The Family Project (Coppins et al. 2011)	BMI z-score Waist circumference Body fat	7 day activity diary Pedometer	7 day food diary	None reported
Family-based behavioural treatment (Croker et al. 2011)	BMI z-score Waist circumference Body fat	None reported	None reported	SPPC (Harter 1985) Children's Depression Inventory (Kovacs 1981) PedsQL (Varni et al. 2003) SDQ (Goodman 1997) Children's Eating Attitudes Test (CHEAT) (Maloney, McGuire and Daniels 1988)

It is accepted that the method of dietary assessment used in this intervention (Y W8? Nutrition check), relied on self-reporting from the children and hence, could be inaccurate. In addition, not all the children returned their food diaries, and not all the diaries which were completed could be assessed. However, the lack of any information on dietary changes has been a criticism made in a systematic review of dietetic interventions in childhood obesity (Collins et al. 2006), so this study did at least attempt to provide a self-report measure of changes in children's fruit and vegetable consumption from the beginning to the end of the intervention. The NOO has produced a report reviewing dietary assessment methods in public health (Roberts and Flaherty 2010). Included in this report are six potential tools that could be used on children's weight management programmes. All six have caveats including the need to validate the tool with all age groups, and where tools have been developed outside the UK, they would need further user testing and validation for UK populations. It seems dietary assessment measures for UK children's populations are developing, but at this stage no sufficiently valid, reliable and practical tools are recommended.

The physical activity measure used in this intervention utilised three validated questions from the HSE. There is currently no 'gold standard' for measuring physical activity (Takken et al. 2003), so the questions were selected based on ease of completion for the age group, and as a performance indicator to see if individuals were achieving the recommended current physical activity targets. Since the intervention commenced the SEF guidelines have been published recommending four measures of physical activity based on a rapid review (Hillsden 2009). Of these four measures only one has been adapted to a version suitable for children; the Physical Activity Questionnaire – Older Children (PAQ-C) (Kowalski, Crocker and Faulkner 1997), which has been validated for use by children aged between 8 and 13 years of age. This questionnaire is a self-administered 7 day recall with 9 items scored on a 5 point scale. The questionnaire is free to use and easy to administer so would provide an appropriate measure to enable results to be compared across programmes whilst providing useful feedback to families. Since the data collection for the RCT finished the Y W8? programme now uses the PAQ-C to measure change in the physical activity levels of the children.

This intervention used an amended version of the Self-Perception Profile for Children (SPPC) (Harter 1985) to measure self-esteem. Problems with self-esteem have been noted in children with weight issues (Walsh-Pierce and Wardle 1997), and the importance of raising self-esteem in weight management interventions has been highlighted (Rees et al. 2009). There are a number of other valid and reliable self-esteem questionnaires available. The Rosenberg Self-Esteem Scale (SES) (Rosenberg 1965) is shorter than the SPPC and takes less time to complete. Both the SPPC and the SES are easy to administer, free to use and validated for use with relevant age groups. The Pediatric Quality of Life Inventory (PedsQL) Measurement Model measures health-related quality of life in healthy children and adolescents using four scales; physical functioning, emotional functioning, social functioning and school functioning (Varni et al. 2003), and is used by a number of programmes (table 8.2). In addition, the Strengths and Difficulties Questionnaire (SDQ) (Goodman 1997), Children's Depression Inventory (Kovacs 1981) and Children's Eating Attitudes Test (CHEAT) (Maloney, McGuire and Daniels 1988) have been used by published RCTs (table 8.2). It would appear difficult to reach a consensus of the measure to use and each programme will have justifications about the decisions they have made. As part of the regional evaluation, Upton and Upton (2009) recommend the Rosenberg SES is applied across the West Midlands regional interventions as it is easy to administer, validated, free, a popular measure and correlates well with other longer measures such as SPPC.

Finally, the SEF guidelines (Roberts, Cavill and Rutter 2009) include participant satisfaction as one of the essential criteria to be collected by weight management programmes. This information is crucial to programme improvement and quality assurance. The Y W8? programme collected this data from both children and parents throughout the feasibility study and the RCT. None of the UK RCTs reviewed in section 4.4 and shown in table 8.2 reported collecting participant satisfaction information.

8.6 Comparisons of the outcomes with other RCTs

As discussed in chapter 5, at the time of developing this intervention in 2005 there was little research on designing effective family-based interventions for obese children utilizing existing behavioural theories which could be implemented in primary care in the UK.

During the early stages of development NICE published guidelines for England and Wales on the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE 2006). This document and the SIGN guideline published in Scotland highlighted the need for well conducted studies in the UK NHS. Since then a large number of papers have been published in this area. However, there are numerous concerns with the quality of these studies mainly around participant numbers and sufficient power, randomisation procedures including concealment and blinding, and poor descriptions of the treatment protocols (Oude Luttikhuis et al. 2009). Therefore, it is important to compare the results of the intervention to set the results in the context of other similar research into childhood obesity treatment programmes.

As the results for the feasibility study and the RCT were very similar, (pre- to post-intervention changes), only the results of the RCT have been compared with other UK based RCTs with children of a similar age at the 3 month post-baseline stage. The 9 month data compares the results from the feasibility study. These UK based RCTs have been described previously (section 4.4). The primary outcome measure of change in children's BMI z-score showed a significant change between the control group and the intervention group, (mean difference = -0.12, 95% CI: -0.09 to -0.16, $p < 0.0005$), over the 12 week intervention period. Further analysis of the results of the intervention group showed children's BMI z-score significantly reduced by -0.11 (95% CI: -0.14 to -0.08, $p < 0.0005$, n=48) over the 12 week period. Using the data from the feasibility study, at 9 months BMI z-score showed a significant change from baseline of -0.15 (95% CI: -0.20 to -0.11, $p < 0.0005$, n=87). Table 8.3 displays these results compared with the results of other similar RCTs.

Table 8.3 Comparison of change in children's BMI z-score from the Y W8? RCT with other UK based childhood obesity treatment RCTs (pre- post-intervention)

Intervention	Design	Comparison between groups at time period stated Mean/median difference in BMI z-score, (95% CI), *p* value
Y W8?	Waiting list control, using RCT design (3 month results) Feasibility study (pre- post-design) for 9 month data	At 3 months post-baseline: -0.12 (-0.09 to -0.16), $p < 0.0005$ At 9 months post-baseline: -0.15 (-0.20 to -0.11), $p < 0.0005$
SCOTT (Hughes et al. 2008)	Intervention or standard dietetic care, using RCT design	At 6 months post-baseline: 0.03 (-0.05 to 0.11), $p = 0.4$ At 12 months post-baseline: -0.04 (-0.17 to 0.07), $p = 0.5$
MEND programme (Sacher et al. 2010)	Waiting list control, using RCT design	At 6 months post-baseline: -0.24 (-0.34 to -0.13), $p < 0.0001$
WATCH IT (Bryant et al. 2011)	Waiting list control, using RCT design	Comparison between groups not published due to small sample size. At 12 months post-baseline: intervention group; 0.03 (-0.05 to 0.11), $p = 0.11$
The Family Project (Coppins et al. 2011)	Waiting list control, using RCT design	At 12 months post-baseline: -0.09 (-0.26 to 0.09), $p = 0.32$ At 24 months post-baseline: -0.3 (-0.62 to 0.02), $p = 0.06$
Family-based behavioural treatment (FBBT) (Croker et al. 2011)	Waiting list control, using RCT design	No significant difference shown so data not published

Table 8.3 displays the results of the change over time from baseline for children's BMI z-score. The results should be treated cautiously as the study designs differ and there are

different follow-up times. However, using the 9 months post-baseline data from the feasibility study which showed children continued to reduce their BMI z-score from baseline by -0.15 (95% CI: -0.20 to -0.11, $p < 0.0005$), the results can be compared favourably with the results for the SCOTT trial, WATCH-IT, the Family Project and FBBT shown in table 8.3. In addition, the Y W8? RCT showed an increase in BMI z-score of 0.01 for the control group over the 3 month period of the intervention. This compares with data from the WATCH-IT programme (Rudolf et al. 2006) who reported a mean increase in BMI z-score of 0.2 over a 3 to 6 month period in children on the waiting list for treatment indicating that children on a waiting list with no intervention may continue to increase their BMI. Thus, the mean reduction in BMI z-score on the Y W8? programme appears comparable with, and better than some, other published evaluations, with the exception of the MEND programme (Sacher et al. 2010).

8.7 Potential adverse effects

The most recent Cochrane review (Oude Luttikhuis et al. 2009) called for future research to report potential for harm of interventions, as well as the benefits. The review identified three aspects for exploration: linear growth, psychological wellbeing and eating disorders. The first two have been reported in this study. In both the feasibility study and RCT height increase significantly as would be expected, and height expressed as a z-score did not change significantly. This suggests the intervention did not adversely affect the linear growth of the children. Regarding psychological wellbeing, the results from the SPPC showed children's self-esteem improved significantly from baseline to 3 months for all of the 4 domains measured. This demonstrates a positive effect on psychological wellbeing.

8.8 Implications for practice and possible future research

Implementation of this type of treatment programme requires a well-trained and committed team, and the co-operation of other health professionals and agencies to refer families into the programme. The use of group-based family treatment of childhood obesity is now common practice in the UK (Upton et al. 2009). However, group-based programmes need to have the ability to be flexible to ensure the needs of individual families can be addressed whilst in the group environment. When reading research papers (Edmunds

2005, Walker et al. 2007, Edvardsson, Edvardsson and Hornsten 2009) and reports (Reddy 2006, Upton et al. 2009, NICE 2006, BMA 2005) on the subject, and from anecdotal feedback gained from meeting with other providers of similar services, there are common themes that emerge which are worthy of further investigation. These issues are discussed below.

8.8.1 Recruitment of families

It was intended to complete the RCT by running two programmes per term. However, this was not possible due to the slow rate of recruitment. This could be due to a number of reasons such as parents and children not recognising the problem and so not seeking help, and health professionals failing to raise the issue of weight with families. A number of papers have reported that parents are often unable to categorise their child's weight status correctly. In the UK, Carnell et al. (2005) documented a study with the results of 564 children. For the parents of the 145 children classified as overweight or obese only 6% described their child as 'overweight' and none as 'very overweight'. These authors suggested the possibility of the parents feeling unable to voice their awareness of their child's weight, or of being able to recognise obesity in other children, but not in their own. Also, in a cross sectional study of 277 British families conducted by Jeffrey et al. (2005) only 25% of parents with overweight children recognised their child was overweight. More mothers than fathers were able to correctly assess their child's weight, and parents were less likely to identify a weight problem in boys. The authors suggested mechanisms for this may include denial, avoidance of the issue or possibly a desensitisation to overweight in the general population. In addition, Mooney et al. 2010 conducted a survey asking about parents' reaction to the NCMP feedback letter received from their local PCT. Ninety-seven percent of parents' with a healthy weight child agreed with the information on the weight of their child. For those parents' with children in the overweight and very overweight categories, 61% disagreed and 32% strongly disagreed. After the survey a sub-set of parents were contacted for a more in-depth interview. For parents in the overweight group their disagreement often concerned the fact their child was only just over the threshold and so the categorisation was unfair. Other reasons parents gave for disagreeing with the results included that their child did not look overweight, they had been

told by a health professional that their child was of a healthy weight and that other factors about the child were unknown to the measurers, resulting in an incorrect categorisation.

Saxton et al. (2009) assessed body size estimation in pre-adolescent children in the UK. The study involved 399 children aged 7 to 9 years being asked to identify their perceived body size by indicating the figure on the children's body image scale (CBIS) most similar in size to themselves. They found that heavier children underestimated their body size, particularly obese girls. Murtagh, Dixey and Rudolf (2006) carried out focus groups with 20 children aged 7 to 15 years of age who had taken part in the weight management programme WATCH-IT in Leeds. The authors report that some children talked of being aware their weight had been a problem for some time but that the cue for change had needed to be an external one, usually coming from their mother. Some of the children appeared to be aware of a delay between their own recognition of the problem and their mother's recognition and/or in her taking action.

A number of papers (Murtagh, Dixey and Rudolf 2006, Dixey, Rudolf and Murtagh 2006) suggest that health professionals should be more pro active in raising the subject of their child's weight with parents. As discussed in section 2.3.6 the *Care Pathway for the Management of Overweight and Obesity* (Reddy 2006) contains evidence-based guidance to help primary care health professionals identify and treat children and young adults who are overweight and obese. The *Care Pathway* offers guidance on the assessment of a child's weight status, exploring the family's readiness to change and management of a child's weight. However, despite tools being available to assist in raising the issue of weight, difficulty in recruitment is a common problem reported by childhood obesity treatment programmes (Upton et al. 2009). This may also reflect the reluctance of parents to take part in this type of family-based treatment programme. Possible reasons could be the parents' fear they will be judged and blamed for their child's obesity and so they may be unwilling to engage in a programme which has an emphasis on parenting (O'Dea 2005). Also, the time commitment could be perceived as an excessive obligation by some families, and not possible within their complex lives, with greater priorities to deal with (Chamberlin et al. 2002). Lastly, a lack of readiness to change may preclude the uptake of the intervention, according to the stage of change model (Prochaska, DiClemente and Norcross 1992).

Recruitment of families by health professionals is now a more viable option as a result of the NCMP, with PCTs now expected to proactively follow-up on children identified as being underweight, overweight or obese from 2010 (Cross-Government Obesity Unit 2010a). In both the feasibility study and RCT for Y W8?, the school nurses referred more families than other professionals, and self-referral was the second most frequent route. This is similar to the findings of Coppins et al. (2011) who recruited similar proportions from healthcare professionals (51%) and self-referral (49%), but in contrast Bryant et al. (2011) had 31% of their participants referred from professionals and 69% self-referred. Both studies found those families who self-referred were more likely to be retained from enrolment to randomisation. This is consistent with the higher completion rate in families who had referred themselves in both the feasibility study and the RCT suggesting self-referral may indicate intention to change (Prochaska, DiClemente and Norcross 1992). Future work could use larger samples to identify whether the method of recruitment is linked to the outcome. This could be completed within existing NHS services for the treatment of childhood obesity, and utilise the distinction between ”active” (i.e. healthcare referral) and “passive” (resulting in self-referral) means of recruitment (Raynor et al. 2009).

8.8.2 Training issues for health professionals

The NICE guidance (2006) on overweight and obesity in adults and children recommended that research is required not only into effective and sustainable interventions but also importantly into the training that health professional staff may require to implement effective strategies. The guidance noted that staff’s enthusiasm and motivational skills are important and the ability to tailor interventions to individual’s needs is key to individual’s success. The BMA in their 2005 position paper on childhood obesity recognised a requirement for health professionals with sufficient time, motivational skills and funding to establish and sustain quality training programmes for NHS staff. They recognise training needs to be offered to both those who deliver treatment programmes and those who may be gatekeepers to services (BMA 2005). Due to the changes being implemented in the NHS and the function of Public Health transferring to the Local Authority in Telford in 2013, there are strong links being formed between the NHS Health Improvement Service, third sector Children’s Centres and Council social services.

Therefore, raising awareness of obesity in families, and training for the identification and treatment of childhood obesity, now needs to be offered among wider groups than just health care professionals. For example, many workers in Children Centres support families in one-to-one and group settings and have the opportunity to raise the issue of weight, assess readiness to change and offer support, advice and referral to treatment programmes when appropriate. Therefore, certainly in Telford, the number of professionals who are potential referrers to programmes such as Y W8? is large. This has implications for the feasibility and cost of training referrers. The DH web tool 'Every Contact Counts' will assist with this (DH 2011c). The tool enables individuals who work with the public to understand the basic health messages, including obesity, and know where to signpost people for further support.

As part of the local sustainability of the programme the author has been responsible for developing a training programme for new members of the Y W8? team who will be Y W8? mentors. Y W8? is a non-clinical intervention and the skills, knowledge and attitudes of the individuals delivering the programmes are very important. The experience of delivering Y W8? of the researcher suggests that recruitment of individuals who have empathy and a non-judgmental approach is essential. Training may be needed to support the interpersonal skills of programme deliverers to be able to establish a positive relationship with both parents and children, deliver appropriate behavioural change guidance and give them the necessary knowledge to ensure they can support and advise families correctly.

Training for professionals referring into programmes is very important as they are the gatekeepers to treatment services (BMA 2005). As stated above, in the case of Telford these referrers are no longer limited to health professionals, so the level of training needs to be appropriate for the background and knowledge of the individual referrers. Referrers need to have an understanding of how to correctly measure a child's weight status, what the results mean and an awareness of how to approach the subject of overweight and obesity with the parents and child. There are external providers, such as MEND and the Weight Management Centre, who offer courses in raising the issue of weight with children and parents but these courses are too expensive to send numerous Children's Centre

workers on, and too time-consuming for GPs and practice nurses to attend. However, a number of papers have highlighted the need for further training and support for professionals referring in to, and delivering childhood obesity treatment programmes. Edmunds (2005) explored parents' perceptions of the responses they received from health professionals when they sought help for their overweight children. The perceived responses from health professionals ranged from a lack of knowledge, not wanting to cause distress, blaming the parent and seeing weight as an individual responsibility. The author recommends that guidance and training is required to assist health professionals in supporting family's who are seeking help with childhood obesity (Edmunds 2005). In response to this need for training the researcher and a colleague have developed a workshop, '*Don't mention the 'F' word*', which includes information on obesity levels in the local area, the short- and long-term consequences of obesity and how to raise the issue of weight with adults, parents and families. During the workshop participants have the opportunity to practice talking to people about weight, albeit in a workshop situation, in an effort to raise their confidence and likelihood they will be able to signpost individuals to local weight management programmes. The BCT of role play, (or demonstrating the behaviour), is used in this workshop as it is known to be useful in building self-efficacy and learning new skills by observing others. The workshop is being offered to health professionals in the local area, children centre staff and student nurses who will be working in Shropshire.

Two papers have provided insight into primary care clinicians' views of their role in childhood obesity. Walker et al. (2007) conducted a small study involving twelve GPs and six practice nurses in the North of England. Both GPs and practice nurses viewed childhood obesity as primarily a social or family problem and thought their role was to raise the issue rather than manage the problem. The clinicians who were interviewed felt the management of childhood obesity was too difficult due to the sensitive nature of the subject, the lack of evidence-based effective treatment programmes and their view that the responsibility for a child's weight lies with the parents. A study by Edvardsson, Edvardsson and Hornsten (2009) conducted in Australia reported on maternal and child health nurses' experiences of raising the issue of children's weight with parents. Nurses reported difficulty in talking to parents about their child's weight especially if the parents themselves were overweight. Nurses commented on the need to be sensitive, the risk of

offending parents and the necessity to use tactful language. Nurses also emphasised the importance of their relationship with the parents and reported concerns that raising the issue of a child's weight could threaten this relationship. Story et al. (2002) conducted a study in the USA and reported the results of a survey of attitudes, skills and training needs of paediatricians, paediatric nurse practitioners and registered dieticians. Areas the health professionals perceived they had low skills in were the use of diagnostic tools, the application of behavioural management skills, guidance on parenting skills and addressing family conflicts, all of which are relevant to the skills of effective referrals to childhood obesity treatment programmes.

Drawing on research from the UK, as well as Australia and the USA, it is possible to conclude there is a need for good quality training and support for health professionals working in the field of childhood obesity, and this could be the focus of future research. Research could explore the content of training required, how the training could be delivered and who should receive the training. This should improve the number of families receiving appropriate information regarding weight issues and increase the numbers of families being referred in to treatment programmes when appropriate. As a starting point research in to whether the DH care pathway (previously described in sections 2.3.6 and 8.8.1) has assisted primary care health professionals in raising the issue of childhood obesity could be conducted, and the results used to plan other resources that could be developed and implemented to assist with this.

In Telford the referrers to the children's weight management programmes are not limited to health professionals so it is suggested all such referrers need to know how to correctly assess a child's weight status, how to interpret the results and how to approach the subject with the parents and child. This is a large task, but with enhanced partnership working within primary and secondary care and Public Health moving to the Local Authorities in 2013 allowing improved relationships with Children's Centres and social services, this challenge is not insurmountable.

8.8.3 Determining the key elements to successful weight management in families

Research exploring the elements of successful weight management in families is needed. The Y W8? programme and other similar programmes are non-clinical services delivered by facilitators from a non-medical background. Previous research has shown the approach of the facilitator and the facilitator-child dynamic is very important in determining whether the child will be successful. For example, Twiddy et al. (2012) conducted a qualitative study with twenty-three families who had previously attended the WATCH-IT programme. In this study the parents and children who were interviewed felt the relationship between the child and the group facilitator was crucial to successful weight loss. The WATCH-IT programme was used in another study (Fassihi et al. 2012), to determine which measures recorded at baseline predicted unsuccessful outcomes. Multivariable regression analysis showed children who had parents who both reported having a weight problem were six times more likely to be unsuccessful compared with children where neither parent reported a weight problem. Barlow and Ohlemeyer (2006) found the most cited reason for non-attendance at a weight management programme was dissatisfaction with the attitude of the health professionals. A review of paediatric weight management programmes was conducted by Farnesi, Ball and Newton (2012) to determine the characteristics that contribute to the relationship between health professionals and families. The review highlighted that communication, health professionals' behaviours and families' perceptions of the care received were key to determining whether the relationship developed between health professionals and families resulted in weight management success. This research suggests that more evidence is needed to understand how positive and supportive relationships can be made between group facilitators and families, and whether this influences success on weight management programmes. This research could draw on the extensive literature regarding group therapy and group self-management programmes. Also, attention needs to be given to understand how to best support families who may require assistance prior to starting a weight management programme to improve the chances that they will be successful. This may include studies that examine interventions aimed at individual families rather than group sessions thereby enabling contact with families to be family-centred and responsive to the family's individual needs (Farnesi et al. 2011).

8.8.4 Cost-effectiveness of programmes and mode of delivery

A detailed analysis of the cost-effectiveness of group-based programmes has not been undertaken at a national level and analysis has not been conducted to compare the effectiveness of group-based programmes with those aimed at individual families. Methodological uncertainties have been raised about such evaluations. When reported, studies tend to use change in the extent of overweight as the outcome measure to calculate cost-effectiveness. In future research it would be useful to obtain information from quality of life questionnaires to assess how valuable any change in degree of overweight is to the individual (cost-utility analysis). To achieve a significant degree of cost-effectiveness the intervention would have to lead to sustained changes in behaviour after treatment has stopped. Analysis would have to take into account the effect of reduced weight on future costs (NICE 2006). Haby et al. (2006) suggest the use of disability adjusted life years (DALYs) saved over a child's lifetime as the outcome measure to assess health benefit in prevention. Although there are methodological uncertainties, it is imperative that cost-effectiveness analyses are conducted alongside effectiveness in future RCTs (Oude Luttikhuis et al. 2009).

One factor influencing the cost of delivering group-based treatment programmes is the children's physical activity session. Incorporating these sessions not only increases costs but limits the accommodation suitable for delivering programmes. There are two RCTs from outside of the UK which suggest that a 'parents-only' focus is an effective alternative to 'family-based' treatment of childhood obesity (Golan, Kaufman and Shahar 2006, Janicke et al. 2008). Indeed, Golan, Kaufman and Shahar (2006) state that the parents-only approach was more effective (this study is described in chapter 4). The current study has been designed as a family-based intervention, with both parents and children attending the group-based programme. This was in response to the information gathered from the focus groups and interviews with parents undertaken during development. However, the parent only session focused on parenting skills, with parents considered to be the 'agents of change' to bring about the required changes in lifestyle. The programme could therefore be adapted easily to a 'parent-only' model, which would be simpler to deliver, requiring fewer resources (i.e. half the number of facilitators, materials, facilities), and would avoid the need for an age-appropriate children's intervention. This would also

possibly make a parent-only intervention applicable to a wider age range (e.g. 5 to 13 years). Depending on commissioning intentions in the local NHS, and future direction from NICE and the DH, funding for this research may be prioritised.

8.8.5 Assessment of parenting style

Future research should also include an assessment of parenting style. One way of measuring parenting style is to assess how parents vary on the dimensions of warmth and nurturance versus control (Darling and Steinberg 1993). Authoritative parents are warm and responsive but are appropriately controlling. Authoritarian parents are emotionally cold and unresponsive, and also over-controlling. Permissive parents impose little control and exhibit overly indulgent (warm) or neglectful (emotionally cold) parenting. Assessing parenting style is important because children of authoritarian, permissive or neglectful mothers are up to five times more likely to be overweight than children of mothers with an authoritative style (Rhee et al. 2006). Golan (2006) has also shown that permissive parenting interferes with weight loss and is associated with more obesogenic environments (Johnson et al. 2012). This may in part be explained by authoritative parents being more likely to monitor their children's food intake (Hughes et al. 2005). Parenting style could be an important moderator of change in BMI z-score, and therefore should be assessed in future studies.

8.9 Sustainability and implementation of the Y W8? programme

Step 4 of the IM framework involves the development of adoption and implementation plans and includes consideration of programme sustainability (Bartholomew et al. 2006). The Y W8? programme was developed and implemented within a NHS organisation, therefore there was no gap between research and normal practice. The programme was also developed by a practicing weight loss mentor so the research was wholly relevant and appropriate for the practitioners' needs (Murray, May and Mair 2010). However, the sustainability of the programme in the current organisation needs to be considered and thought given to how the programme could be implemented in other organisations. The publication, *Lightening the load: Tackling overweight and obesity* (Swanton and Frost 2007), was used to develop local strategies to tackle overweight and obesity in children

and adults during the adoption and sustainability phase of intervention planning. This included ensuring the programme was part of the local Obesity Strategy and the local council's Children's Services Strategy. With changes to the structure of the NHS, and the move of Public Health to the local authority, it is timely to reconsider these strategies to ensure childhood obesity is prioritised and receives funding. In the following sections the sustainability of the programme in Telford, and the potential for sustainability of similar programmes derived from the model of Y W8? in other UK organisations, are considered.

Appendices 40, 41 and 42 document the presentations and posters that have been delivered to raise awareness of the Y W8? programme, academic papers that have been published and prizes that have been awarded to the author and the Y W8? team.

8.9.1 Sustainability in current organisation

Sustaining the programme in the organisation within which it has been developed is important to ensure that families with overweight children in the local area have access to an evidence-based successful weight management programme, and those families that have attended the programme can access long-term follow-up and support. The Normalisation Process Theory (NPT) (Murray et al. 2010) provides a framework to enable programme developers to identify the factors that promote and inhibit the normalisation of complex interventions into organisations, i.e. interventions becoming routine practice. Although a relatively new theory, NPT has been used in mental health settings (Gask, Lever-Green and Hays 2008), treatment of cancers (Coburn et al. 2008) and in the implementation of telecare (Mair, Hiscock and Beaton 2008) and e-health systems (Gagnon et al. 2008). A simplified version of the NPT has now been configured as a web enabled toolkit (http://www.normalizationprocess.org) to allow users to apply it in real world settings (May et al. 2011).

The NPT framework can be used to identify and understand the ways that people make sense of the work of implementing and integrating a complex intervention (coherence); how they engage with it (cognitive participation); enact it (collective action); and appraise its effects (reflexive monitoring). According to NPT, through these processes the complex intervention becomes embedded in routine practice and ceases to be a 'complex

intervention', and instead becomes part of the normal activities that the workforce delivers. The four constructs of NPT are used in the sub-sections below to explore how they could be used to achieve sustainability of the Y W8? programme in the current organisation.

8.9.1.1 Use of NPT construct – Coherence

To enable local professionals to understand how the programme could be implemented and integrated it would be imperative to seek opportunities to meet with the local workforce at team meetings, events and ad hoc appointments. Information regarding the programme would need to be given including how it is run, where, when and an overview of the contents. Information regarding the accommodation and facilities required to run a programme would be required as would an estimate of the costs. It would be important to give professionals an overview of the Telford and Wrekin childhood obesity pathway and identify how this programme fits into the pathway. Through this the partners involved in the programme could be identified and possible links could be made between organisations. This dialogue would also give an opportunity to explore with professionals the skills and knowledge they feel they require to fulfil their role, whether they are referrers, potential deliverers, decision makers, etc and would highlight gaps in skills and knowledge where training needs to be offered.

8.9.1.2 Use of NPT construct – Cognitive participation

Coverage in the local press would highlight the service to the public. This would hopefully have a dual effect. Firstly, the number of families who self-refer to the programme should increase. Secondly, during public consultations carried out by local commissioners and Clinical Commissioning Groups (CCG) the service would be described and peoples' experiences talked about, therefore, increasing the likelihood of further funding and sustainability. The NCMP is another means of engaging with families about their child's weight. Using case studies showing families who the public can associate with could be targeted at families who have received a letter from the NCMP stating their child was in the overweight or very overweight range would be a mechanism of engaging with families in a non-judgemental way. In conjunction with this, developing a website would be a good way of allowing both families and professionals access to information about the programme.

The website could contain details of the service, where it is running and how to get involved. It could also include user testimonials, success stories and clips of the activities used in the weekly intervention.

8.9.1.3 Use of NPT construct – Collective action

The simplest way for professionals to understand how the programme works, what the programme actually is and how their role influences the intervention, would be to experience it for themselves. It would be impractical for a large number of people to attend sessions but key programme champions could be identified and invited to attend sessions. They would be asked to disseminate their observations and their thoughts regarding how the intervention fits with their team or organisation to their work colleagues. Alternatively, a 'taster session' could be developed and delivered in the manner of a training session which would inform individuals regarding the format and content of the programme, and also allow them to experience a number of the interactive demonstrations and understand how the intervention seeks to deliver the key messages. Finally, a DVD could be produced showing an abstract of a session which would raise the awareness of what sessions entail and summarise the key objectives.

8.9.1.4 Use of NPT construct – Reflexive monitoring

The results of the programme, case studies and family testimonials could be disseminated and presented at meetings where referrers, commissioners and decision makers were present to raise the profile of the service and provide information regarding effectiveness. In addition, reports regarding how the intervention supports policies and assists the Trust in reaching targets would be important to be presented to the local Trust. Feedback could be provided to referrers regarding the success of the families they have referred to reinforce the effectiveness of the programme and maintain motivation to keep referring families. Providing information to be included in reports such as the West Midlands Regional Evaluation (Upton et al. 2009) is a good opportunity to compare results and costs against other services. The evaluations are disseminated throughout the region and provide a mechanism for having programme results externally evaluated and presented to different audiences than can normally be reached. Finally, if the programme was

implemented by other organisations it would demonstrate that other areas consider the programme to be effective and beneficial to their local population.

The Y W8? programme was given recurring funding by Telford and Wrekin PCT commissioners for the length of the current contract which is due to finish in April 2013. Although future funding has not been confirmed, 'Reduce excess weight in children' has been identified as a priority of the Telford and Wrekin Health and Wellbeing board so interventions such as Y W8? should be given funding to support this priority. Although the intervention is in the implementation stage, it would be useful to use the NPT framework to understand how the programme can continue to be sustained in the organisation, and identify constraints and challenges that need to be overcome. The formation of a steering group, such as that used in step 1 of the development of the programme, to implement the toolkit would be very important to ensure all professionals involved in the programme have the opportunity to influence the outcomes from the toolkit, and contribute to future work that might arise from using the toolkit. This steering group could also include families who have been participants as the toolkit is suitable for use by those who have received the intervention. This partnership approach would also raise the profile of the service and perhaps re-engage those professionals who have lost contact with the service. The interpretation of the results could be shared with the members of the steering group to formulate a plan of action to ensure sustainability of the programme. Using a steering group approach to implementing the action plan would demonstrate to local commissioners the support for the programme, and use of the toolkit would display a willingness to make changes and work in different ways where necessary.

8.9.2 Implementation of Y W8? in other UK organisations

The Y W8? programme has been used as the basis for the ACES (Active Children Eating Smart) programme being delivered by NHS Greater Glasgow and Clyde. The local team in Glasgow have amended the programme in-line with local needs and feedback from health professionals working the area. The Y W8? programme developer assisted the Glasgow team in developing a training programme for the local 'coaches' who deliver the programme, and the Y W8? manual was used as the foundation for the ACES manual. In response to local feedback their programme includes more practical food sessions and

they have linked with their local leisure providers to offer the families on ACES further activities and free introductory sessions. The Glasgow team are also recruiting children from 5 to 15 years of age, although after difficulties in delivering to such a wide age range they have now developed Teen ACES for 14 and 15 year olds. Being based in a large city and surrounding area means ACES is run on a much larger scale than in Telford. They have trained 22 coaches and 22 food coaches who deliver up to 10 programmes at any one time. The distance between the areas where ACES is delivered has meant a 'coach hotline' has been provided to offer individual support when required, and local areas have had to identify contacts and pathways to support coaches in relation to child protection and other issues. The work carried out with Glasgow provided an insight into how different areas implement programmes, and has demonstrated that the programme can be replicated in another area without the direct assistance of the programme developer, and delivered at much greater scale. The Glasgow team have not yet released any results of the ACES programme so it is not possible to evaluate the success of the programme nor to compare its effectiveness against the Y W8? programme.

With hindsight it would have been useful to have used a framework such as the NPT toolkit prior to, and during the implementation of, ACES in Glasgow, and it is a framework the researcher would recommend if the Y W8? programme was transferred to another area. According to May and colleagues (2010) the online toolkit shows the constructs and components of NPT translated into simple statements that assist the group responsible for delivering the new programme through implementation problems. Application of the theory through the toolkit focuses thoughts on the work that people do and helps the group make pragmatic decisions about how the intervention will fit into routine work by; initiating the intervention, agreeing it is a legitimate part of their work, joining in the delivery of the intervention and continuing to support the intervention (May et al. 2010). The toolkit also supports the group in reviewing and generating policies and procedures to support the intervention. This is a key component of implementing new interventions as evaluating whether changes can be made to existing policy and procedures, or new ones developed, is vitally important in ensuring interventions are adequately supported by the host organisation.

As a result of the success of the programme in Telford, and its initial implementation in Glasgow, it is likely other organisations may seek to adopt the programme. A number of Trusts in the West Midlands have shown interest and are keen to have a programme such as Y W8? running in their area. Based on the analysis above, it would be appropriate to test the use of the NPT framework as an implementation planning tool.

8.10 Suggested changes to the Y W8? programme

Both the feasibility study (chapter 6) and the RCT (chapter 7) demonstrated that both parents and children felt on the whole positive about the Y W8? programme. However, feedback from families and the Y W8? mentors delivering the programme has led to changes being suggested for the programme. The main concern raised by parents in the semi-structured interviews conducted at the end of the feasibility study was anxiety related to how successful they would be in continuing with the healthy changes they had made whilst on the programme. This type of feedback regarding post-intervention maintenance has been reported previously. Staniford et al. (2011) carried out a qualitative study into childhood obesity treatment programmes. The results showed the recipients of the treatment programmes perceived the post-intervention maintenance process differently from the deliverers of the intervention, with the recipients reporting a need for ongoing support and the deliverers aiming to promote autonomous maintenance of behaviours. This gives a rationale for the need to provide follow-up appointments for families at regular intervals to offer support and motivation for sustained behaviour change. Within the current intervention amendments could be made to address this issue in a variety of ways. For example, the structure of the programme could be changed to extend the length whilst the intensity reduced. In the USA, the Epstein team have shown positive results from its programme which supports families for 6 months with the intensity of the programme reducing with time; 16 weekly meetings are followed by 2 biweekly and 2 monthly meetings (Epstein et al. 2000).

Alternatively, other modes of supporting families could be offered to enhance the sustainability of changes. Saelens et al. (2002) used a computer programme to reinforce behaviour change and enable participants to create individualised action plans. Telephone contact was also used to address weight change since the last call and to

provide feedback and support for achieving goals. Compared with typical care comprising a single appointment with a weight counsellor, participants accessing the computer programme and telephone support evidenced better change in BMI z-score at the end of the intervention and at 3 month follow-up. Estabrooks et al. (2009) compared three groups; families who received a workbook to promote increased physical activity, reduced sedentary behaviours and healthy eating, families who received the workbook and had two group sessions and families who received the workbook, group sessions and after completing the programme 10 follow-up sessions delivered via interactive voice response (IVR). Only children in the IVR group decreased their BMI z-score from baseline to 6 months and at 12 month follow-up. This suggests that use of interactive technologies can improve the results seen in childhood obesity treatment programmes and may be useful in offering extended support at the end of interventions. This type of technology could also increase the reach of interventions and could be cost-effective when compared to normal treatment programmes. For example, using data from the NCMP we know there are approximately 600 children in year 6 who are in the overweight and obese category in Telford. Using this figure it is estimated there are 3600 children in the borough who are between the ages of 8 and 13 who would be eligible for the Y W8? programme. The programme is currently commissioned to engage with 72 families each year – 2% of the estimated population. Technology, such as described above, could provide a cost-effective means of extending the reach of the programme and enable more families to engage with a childhood obesity treatment programme.

Parents were also concerned about their child reducing their physical activity levels once the programme had finished, particularly due to the cost of activity sessions in the local community. Changes to enable both parents and children to take part in activity sessions have already taken place in response to their feedback. Y W8? now offers free family physical activity sessions during the week staffed by activity instructors who have delivered the Y W8? programme who can offer support and advice to family's when necessary. A rolling programme of activities has been introduced to appeal to different preferences. The programme includes martial arts, noncontact boxing, gym sessions and Zumba. This addition to the programme is offered free to the families and at various locations across the borough to remove barriers concerning cost and transport. The activity sessions are able to be offered free to families due to the partnerships formed and

support that was agreed during step 1 of the IM process when the steering group was meeting. Other similar programmes also use this type of model. For example, the MEND RCT included 12 weeks of free access to physical activity at the end of the standard programme (Sacher et al. 2010). MEND also suggests deliverers of their programme offer physical activity sessions to families once they have finished the programme. However, this depends on the resources and facilities available to those areas who have commissioned the programme.

8.11 Summary and conclusions

This study has demonstrated the successful development and implementation of the Y W8? childhood obesity treatment programme. The study was developed using the IM protocol. This was a strength of this research as it ensured theories, evidence and user views were integrated and developed into an intervention to be delivered to local families. The BCTs used in the intervention were classified using the CALO-RE taxonomy (Abraham and Michie 2008). This is another strength of this research enabling clear, precise reporting of the programme and enhancing the possibility of identifying the effective ingredients within the intervention (Michie et al. 2009b).

A feasibility study was carried out and evaluated using a mixed-methods approach to enable a detailed process and outcome evaluation to take place. This sought to gain evidence of the beneficial effects of the programme on child and parental health status, and the acceptability of the programme to families. A further strength of the research is that data collection and evaluation was in line with the SEF for weight management interventions (Roberts, Cavill and Rutter 2009).

Finally, agreement was gained from key stakeholders to conduct a RCT to measure the programmes effectiveness on key health outcomes. Being able to successfully carry out the RCT is a particular strength of this research. In the latest Cochrane Review (Oude Luttikhuis et al. 2009) only two of the RCTs reviewed were from the UK. In the updated literature review for this research (section 4.4) five RCTs were highlighted. This demonstrates the evidence base is growing and this research adds to the evidence base concerning lifestyle interventions for overweight and obese children.

To add evidence to the strength of the intervention the economic evaluation reported in the West Midlands regional evaluation of weight management programmes for children and families (Upton et al. 2009) was presented and showed the Y W8? programme is a low-priced intervention when compared with other similar projects. Comparison of the outcomes of the RCT with other UK based RCTs with children of a similar age show the mean reduction in BMI z-score on the Y W8? programme is comparable with, and better than some other published evaluations. Finally, whilst adding to the evidence base, the treatment intervention described in this thesis differs from those being researched in the UK, and contributes in an original way, in that it is a locally developed programme, utilising the knowledge, expertise and strengths of the local community to assist in its development resulting in a successful intervention.

Chapter 9 Final conclusions

9.1 Introduction

This chapter summarises how the thesis achieved the aim and objectives of the research, and uses the NPT framework to consider how far the research has been embedded by the local NHS and how it has impacted on the priorities for the local area. The chapter continues by discussing the future directions of the programme in Telford including the opportunity for the team to develop a similar programme for a younger age group. The place of programmes such as this within public health is considered including their affordability, scalability and reach, and the challenges and benefits of applied research are discussed. Finally, the unique contribution this research makes to the evaluation of lifestyle change programmes for overweight and obese children is presented.

9.2 Summary of how the thesis addresses the aims and objectives of the research

This thesis aimed to apply a systematic approach to intervention development and evaluation. It utilised research evidence from published evaluations of similar interventions and theory of behaviour change processes to underpin the intervention, whilst also incorporating end user input at all stages.

There were five objectives for the study:

1. To use Intervention Mapping to develop a weight management intervention promoting healthy diet and exercise for obese young people and their families
2. To pilot the intervention with obese young people and their families to test the feasibility and acceptability of the programme
3. To conduct a RCT to evaluate the effectiveness of the intervention
4. To carry out preliminary tests of a number of hypotheses related to improving health behaviours and health status of the participants
5. To examine the features of the programme which are likely to determine successful implementation and sustainability in routine services

The development of the Y W8? childhood obesity treatment programme using the IM approach, described in chapter 5, met the first objective. The second objective was met through carrying out a feasibility study with 122 children and their families (chapter 6). Objectives 3 and 4 were addressed through conducting a RCT with 114 children and their families. Chapter 7 documents the results of the RCT and the outcomes of the testing of a number of hypotheses related to improving health behaviours and health status of the participants. Objective 5 was discussed in chapter 8.

9.3 The impact of Y W8? in Telford

Telford was one of the first areas in the UK to develop its own local childhood obesity treatment programme in response to growing concern from local health professionals and local child health data. This thesis has documented the development, delivery and evaluation of this programme, and demonstrates how local expertise, resources and knowledge can be combined to produce effective public health initiatives that are valued by the community and address important local health concerns. However, there were implementation problems that needed to be addressed. The four constructs of the NPT framework previously described in section 8.9 are used in this section to describe how the Y W8? intervention was successfully implemented in the current organisation and what obstacles had to be overcome.

9.3.1 Use of NPT construct – Coherence

As described previously the rising prevalence of obesity in children in the UK has resulted in a significant policy response from Government over a number of years. Combating childhood obesity has remained high on the Government agenda and even with changes in Government and the reduction in Public Health programmes due to financial constraints, it remains a priority for local areas to offer interventions to help families with weight management (DH 2011b). This national call has been responded to locally at a strategic level. The local NHS has chosen reducing childhood obesity as one of its top ten World Class Commissioning (WCC) priorities (NHS Telford and Wrekin 2010) and is included in the local area agreement (Telford and Wrekin Children's Trust 2009). Additionally, it remains a focus in both the *Annual report for NHS Telford and Wrekin* (NHS Telford and Wrekin 2011) and the *Public Health Annual Report for Telford*

and Wrekin (Telford and Wrekin Council, NHS Telford and Wrekin 2011). Recently the Telford and Wrekin CCG, which will be in place from April 2013 and be responsible for commissioning local health services, has identified 'Reducing excess weight in children' as one if its Health and Wellbeing priorities (NHS Telford and Wrekin 2012).

It would seem that these national policies, combined with the local data from the NCMP and the willingness of the local NHS to invest money in a childhood obesity treatment programme have assisted with the successful implementation of Y W8? Working together with the local Children's Obesity Commissioner the researcher has developed the Telford and Wrekin childhood obesity pathway and the Y W8? programme is integral to this. The challenge is now to ensure the programme continues to be commissioned as the structure of the NHS changes. To enable local CCGs to make commissioning decisions information regarding the programme structure, content, effectiveness and costs will need to be disseminated, along with user evaluations and local health professional feedback.

9.3.2 Use of NPT construct – Cognitive participation

The use of the IM approach was integral to the successful implementation of the Y W8? programme in Telford. It ensured local stakeholders and health professionals were involved in the planning and implementation of the programme. This commitment at both a strategic and delivery level helped to embed the programme in the local organisation and raise awareness of the programme with key individuals. Formation and management of the steering group was not always easy. Key health professionals, whose input was critical to the development of the programme, were often difficult to liaise with and had very busy diaries making it hard to arrange meetings at a suitable time for all attendees. But when many of the attendees were present managing the group could be challenging. Members from different organisations often had conflicting priorities which the researcher had to manage. For example, members from the local authority wanted the focus to be on physical activity and using their facilities at a cost to the intervention, while the dietician and paediatrician felt the focus should be more clinical despite the need for the service to be delivered by non-clinicians, and the member from education wanted the intervention to support the Healthy Schools agenda and work with groups of school children in the classroom. Using the IM approach made

this easier to manage as the researcher was able to present the results of the needs assessment, focus groups, interviews and literature review, and steer the group to make decisions based on this evidence. There was also some deliberation regarding where the intervention would run. Members of the local authority wanted to use the local leisure centres, but this would have been charged at the normal rate. A member from the Further Education college offered their new sports facilities at a vastly reduced rate so the decision made was based on both cost and the quality of the facilities available.

Once the intervention was developed, and the feasibility evaluation study was planned, the steering group proved very useful as the first referrers to the programme. As members of the steering group their insight into the programme meant they could explain to families about the programme and answer their questions. Being able to engage with families with all the information should have assisted families accessing the programme and managed their expectations concerning the content of the intervention. They also acted as 'local champions' for the programme by telling their colleagues about it to boost the number of referrals, inviting the researcher to team meetings to talk about the programme and displaying posters and fliers about the programme.

9.3.3 Use of NPT construct – Collective action

The Y W8? programme has been developed as a family-based group intervention for 8-13 year old children who are overweight or obese. The programme was designed to be delivered in a community setting by non-specialists. It was decided to use this model as the Health Improvement team were successfully delivering an adult weight management programme using similar programme content which was being delivered by non-specialists, so the staff were familiar with using community settings. This option provided a low-cost alternative to training and using clinical staff. Once step 3 of the IM process had been completed it became clear that existing members of the Health Improvement team were qualified, had the skill set to deliver the programme and were keen to be involved. It also made the intervention easier to implement as the staff required to deliver the programme were readily available and had been involved in the development of the content of the programme as part of the steering group. The other UK childhood obesity treatment programmes using non-specialists to deliver the programme are MEND (Sacher et al. 2010) and WATCH IT (Bryant et al. 2011). The

use of non-specialists allows programmes to be scaled up easily, delivered at a lower cost, enables programmes to run in community settings and makes use of the local workforces' skills and interests.

Once the feasibility study was running a number of members of the steering group were keen to understand more about the programme by attending sessions. This was a potential problem and had to be managed carefully and completed over a period of time as it was impractical to have more than one person as an 'observer' at each session. The dietician was the first member of the steering group who attended the sessions and she chose to follow a group for the whole twelve weeks. She then acted as a programme champion and the intervention continues to receive referrals from her.

9.3.4 Use of NPT construct – Reflexive monitoring

Since the intervention was developed and began delivery the reduction of childhood obesity and delivery of weight management programmes for children has remained a priority for the local area. In 2009 the Children's Obesity Commissioner commissioned research on child health and obesity in the local area. The research scope included consultation with families, local professionals and stakeholders about the Y W8? programme, and research into the NCMP including contacting parents who had received a letter stating their child was in the overweight or very overweight category. In the report, *Child Health and Obesity Research* (Ci Research 2009), feedback from local professionals regarding the programme was very positive;

"It's a family lifestyle approach to weight management which I think is the way to go. The whole family approach at Y W8? is fantastic" – School nurse

"It's an intelligent and well-thought out programme" - Paediatrician

"If anyone comes to us now with a child with a weight issue we always refer on to the programme" – Leisure Services Manager

After the first year of the feasibility study the researcher was given opportunities to present information about the intervention and the existing results at meetings where

referrers, future commissioners and decision makers were present to raise the profile of the service and provide information regarding effectiveness. As further Government White Papers and policies were being published throughout the implementation of the intervention the researcher was provided with ample opportunities to provide senior managers and directors with information regarding how the intervention supports policies, and assists the Trust and local authority in reaching targets. The West Midlands Regional Evaluation of Weight Management Programmes for Children and Families (Upton et al. 2009) provided a good opportunity to compare the results and costs of the Y W8? programme against other regional programmes. The West Midlands report was disseminated widely and provided a mechanism for having programme information and results externally evaluated and presented to different audiences.

9.4 Future directions for intervention development and evaluation in Telford

It is notable that this is the only RCT, of which the author is aware, conducted within the service resources of the NHS. This may be because of difficulties in committing resources for sufficient time to run both the intervention and the evaluation. There can be ethical concerns if a childhood obesity treatment programme proves successful when evaluated with simple pre-post designs. The next stage of evaluation by an RCT may be difficult to justify when no other suitable options exist (Watson et al. 2012). Whilst the RCT is regarded as the gold standard design for research, the practical reality is that high quality service evaluation may need to be used and accepted to ensure services are improved, their results shared and allow families to access treatment programmes in their locality in a timely manner. The changes in recent years in commissioning and competition between providers in the NHS may exacerbate this problem as Ham (2008) reported that child health services 'risk being further fragmented by policies promoting competition between providers' (p. 806).

In Telford the delivery of weight management programmes for children and their families has been identified as a priority outcome. Commissioning intentions report that the Y W8? programme has been commissioned by Telford and Wrekin PCT for another year albeit on a reduced budget. The Y W8? programme has been selected above MEND and MoreLife (formely Carnegie Weight Management) due to the programme being able to be commissioned at a lower price than the others due to the programme's existing

networks in the local community, and the credibility it has with local health professionals. The programme is also tried and tested in the local area, has proved effective and the name is well-known to the local population and local health professionals. In the future the team intend to improve the evaluation of the programme by attempting to collect longer term follow-up data from participants to be able to evaluate the medium and long term effectiveness of the intervention and make comparisons with other similar programmes.

The childhood obesity team in Telford have also been commissioned to develop a 'Y W8? Junior' programme for families with children aged 4 to 7 years of age who are overweight for their height. Previously MEND 5-7 has been commissioned and delivered in the area but the cost to buy this programme is now prohibitive. The researcher will lead the team to develop the intervention and intends to use the IM approach for the development of the programme to ensure user views and expertise from local professionals who work with this age of children are combined with the knowledge gained from running the Y W8? programme to produce an intervention suitable for this age group. It is intended to use the NPT framework to implement the programme and focus on how it can be sustained in the organisation.

9.5 Childhood obesity treatment programmes within public health

Previous and more recent Government policy suggests the need for evidence-based childhood obesity treatment programmes to be available for the large number of overweight and obese children in the population. However, there are a number of factors that need to be considered to achieve this including reach, affordability and scalability. Treatment programmes located in clinics often have limited reach and are costly which prohibits their scalability. Whilst those delivered in community settings are often cheaper, (see table 8.1 for example costs of programmes), their reach and scalability is still questionable.

When considering the reach of programmes it is useful to revisit the scale of the issue in the UK. Overweight and obesity affects approximately 30% of the child population in England which equates to 3 million children (IASO 2008). The cost to roll out programmes with the capacity to meet this requirement would be unfeasible. In real

terms the Institute of Education Review of Interventions recorded 51 schemes currently or recently run in England, and these typically included 60 to 100 children each, per year of operation (Aicken, Arai and Roberts 2008). Therefore, only 4000 to 5000 children were, or are, benefiting from the childhood obesity treatment interventions being delivered in England each year. Clearly, not all families who are eligible for these programmes would want to be involved in an intervention for many different reasons. However, if more programmes were being delivered in communities and attendance at interventions was more commonplace, it might change parents' and children's attitudes towards programmes, and improve the recruitment issues faced by many programmes. Nevertheless, using the models currently being delivered in the UK the magnitude of finances required to scale up programmes in order to reach a large proportion of those eligible to receive an intervention would be prohibitive to commissioners when there are so many other demands on their limited resources. The Audit Commission, the Healthcare Commission and National Audit Office (2006) identified this in their report *'Tackling child obesity: first steps'*. They noted the lack of ring-fenced money and the short-term approach to funding to support the childhood obesity target and the need for collaboration and local partnerships involving a variety of different public and private bodies.

The scaling up of interventions in communities would require them to be delivered in settings within reach of most people who require them. This would help to address health inequalities and allow access for those who live in disadvantaged areas. For such a delivery model to be achievable and sustainable organisational resources would need to be assured, and the large workforce required to deliver programmes would need to be trained and supported. Partnership arrangements would also need to be explored as multi-agencies working to tackle obesity levels will allow much more to be achieved than working in isolation (Swanton and Frost 2007). In a review of the best available evidence of effective multi-agency and partnership approaches to preventing and managing childhood obesity Rice, Fauth and Reeves (2011) list the benefits of partnership working as:

- sharing financial and other resources that may be required to deliver a particular intervention

• sharing information and materials, for example, population data or campaign materials across several agencies
• better access to hard-to-reach audiences where one partner may have greater influence or credibility
• increasing buy-in from other influential partners due to greater collective 'pulling power'.

(Rice, Fauth and Reeves 2011 p.2)

In support of this Collie-Akers and Fawcett (2008) suggest there is limited evidence that any single intervention will affect population-health improvement in diverse contexts. They suggest that effective community interventions will need to consist of various changes in programme, policies and practice. A protocol such as the NPT framework (Murray et al. 2010), which has been applied to the Y W8? programme in section 8.9 and section 9.3, could be used to support the changes that need to be made to embed programmes in routine practice.

9.6 The challenges and benefits of applied research

This thesis has described an applied research project conducted within the NHS. The intervention was designed and developed in a primary care setting and implemented in a local community. This process of applied research has meant the research has been conducted within a field which is a serious challenge to public health, whilst participants have been able to access an intervention and influence the development of it, and the programme has been able to demonstrate effectiveness in a real world setting. With the structure and functioning of the NHS changing dramatically and challenges to public health finances, policy-makers within childhood obesity cannot wait for lengthy trial outcomes before interventions are implemented in practice (Watson et al. 2012). The type of applied research in this thesis has allowed obesity research and policy to go hand in hand. Whilst high-quality RCTs are published in high-impact journals their potential for implementation in real world settings is often untested and it is unknown whether they will work in practice. Conversely, for services that are effective in practice it may not be ethically viable to conduct an RCT as access is required for all eligible children, and randomisation to an alternative treatment is not acceptable. Additionally,

many services are the only ones running in their area so they need to be inclusive of all obese children and not have the strict inclusion and exclusion criteria of RCTs. Interventions, such as the one in this thesis, have overcome the randomisation issue by using a WLC group, but this still requires participants to wait a certain period of time prior to starting their treatment and this is not always acceptable to commissioners who are buying services, or to families who are seeking help. To enable this model to be utilised the intervention also needs to be funded for a sufficient duration, and this is not always possible, especially in the present financial climate. For those services that are unable, or do not want, to embark on formal research then service evaluation is usually conducted, but may only be disseminated through the 'grey literature'. This can make accessing the information regarding the services difficult and dissemination of good practice can be challenging. In the case of this programme, the author has sought out, and been invited to present, at a number of local, regional and national conferences to disseminate the findings of the Y W8? programme (see appendix 40). Two papers have been published (appendices 41 and 42), and details regarding the programme have also been included in regional (Upton et al. 2009), and national (Aicken, Arai and Roberts 2008) evaluations. Information about the programme has also been input into the database of interventions on the NOO website. This is a national database for weight management, diet and physical activity interventions.

Using applied research also means the available evidence base can be combined with the needs of the area and the resources and facilities available in the community, to develop a unique intervention for the locality based on best practice. However, it is not without its challenges. It takes time to develop an evidence-based programme, and key funders and decision makers in organisations wanting to deliver programmes may not understand or value this. For example, the Y W8? programme took nearly a year from its start point until the pilot study took place. At the time this was acceptable as the time for development had been planned and agreed in advance. However, other organisations may be seeking a quick answer to their needs, especially if they have short-term funding, so allowing for this period of development is not always acceptable. Also, service delivery responsibilities often have to take priority. Programme leaders can often be put under pressure to achieve targets and meet funder's expectations, and the research aspect of the service has to come second. As already discussed it can be difficult to follow strict research protocols when interventions are delivered in real-world

settings. For example, the treatment programme might need to be inclusive of all obese children regardless of their medical conditions or learning ability. This can be overcome by separating the research from the service and only including children in the research aspect of the programme who meet the inclusion criteria (Watson et al. 2012). Finally, ensuring the research is integrated into complex organisations and policy environments can be a challenge. As discussed previously, using a framework such as the NPT can assist with this, and ensure programmes are embedded into routine practice.

9.7 Unique contribution of this research to the evaluation of lifestyle change programmes for overweight and obese children

The Y W8? feasibility study and RCT described in this thesis have added to the evidence-base for how the behavioural management of childhood obesity can be conducted and implemented within the UK NHS. There is a general agreement in the literature that there is a lack of evidence from well conducted RCTs on the treatment of childhood obesity (NICE 2006, SIGN 2003, Oude Luttikhuis et al. 2009). This RCT offers evidence to support the use of family-based treatment programmes in the treatment of childhood obesity and displays positive results in the short-term. The development of this childhood obesity treatment programme differs from those being researched in the UK, such as MEND, and contributes in an original way, as it used the IM approach to integrate theories, evidence and local stakeholders and user views to develop an intervention to deliver to local families. The programme was delivered in a community setting by non-specialists and has used the resources and capacity of the local community to ensure sustainability. Further, the behaviour change techniques used in the intervention were classified using the CALO-RE taxonomy (Abraham and Michie 2008) enabling clear, precise reporting of the programme and the data collection, which will enable others to replicate or build upon the methods used.

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Appendix 1 Evidence table for studies discussed in chapter 4 section 4.3

Author(s) and year: Epstein, Paluch, Gordy and Dorn 2000 **Location:** USA **Aim of study:** To compare decreasing sedentary behaviour with increasing physical activity in a childhood obesity treatment programme **Study design:** RCT	**Setting:** Childhood obesity research clinic at university **Participants:** 90 obese children **Inclusion:** Aged 8-12 years of age, between 20% and 100% overweight, neither parent more than 100% overweight **Exclusion:** Family member participating in an alternative weight-control programme, current psychiatric problem, dietary or exercise restrictions	**Intervention(s):** 6 month treatment including 16 weekly meetings, 2 biweekly and 2 monthly meetings with 4 treatment groups: Low dose decrease sedentary behaviours (LDSB) High dose decrease sedentary behaviours (HDSB) Low dose increase physical activity (LDPA) High dose increase physical activity (HDPA) **Control:** No 'non-intervention' control **Sample sizes:** Assessed for eligibility = 171 Randomised: 90 LDSB = 23 HDSB = 22 LDPA = 22 HDPA = 23	**Anthropometry measures:** Percentage overweight at 6 months Percentage body fat at 6 months **Diet measures:** Not measured **Physical activity measures:** Fitness (cycle ergometer) Physical activity questionnaire (based on the Minnesota Leisure Time activity survey) **Wellbeing measures:** Not measured **Other measures:** Socioeconomic status (using the Hollingshead Four-Factor Index of Social Status) **Follow-up periods:** 12 and 24 months (after start of programme) **Method of analysis:** Analysis of variance with between-subject factors of cohort and a repeated measures within-subject factor	**Anthropometry results:** Mean change in percentage overweight at 6 months: LDSB: -22.4±12.6% HDSB: -27.4±10.7% LDPA: -25.6±8.1% HDPA: -26.4±10.5% Mean change in percentage overweight at 2 years: LDSB: -11.6±21.9% HDSB: -14.3±16.9% LDPA: -12.4±13.3% HDPA: -13.2±16.4% All changes in mean percentage overweight from baseline to six months and to 2 years across all groups are significant ($p<0.001$) **Attrition:** 2/90 attendees (2%) dropped out at 6 months 12/88 attendees (14%) dropped out at 2 years	**Limitations identified by authors:** Lack of 'diet-only, no physical activity' control group Self-reporting of physical activity behaviours

Author(s) and year: Epstein, Valoski, Wing and McCurley 1990 **Location:** USA **Aim of study:** To evaluate the long-term effectiveness of a childhood obesity treatment programme and assess the effectiveness of targeting children and/or parents in the reinforcement for weight loss and behaviour change **Study design:** RCT	**Setting:** Childhood obesity research clinic at university **Participants:** 76 obese children **Inclusion:** Aged 6-12 years of age, greater than 20% overweight, triceps skin fold greater than 95th percentile, both parents living at home, at least one obese parent **Exclusion:** Current psychiatric problem	**Intervention(s):** 8 month treatment including 8 weekly meetings and 6 further meetings over the next 6 months with 3 treatment groups: Group 1: child and parent target for reinforcement Group 2: child target for reinforcement Group 3: non-specific target for reinforcement **Control:** No 'non-intervention' control **Sample sizes:** Assessed for eligibility = 185 Randomised: 76	**Anthropometry measures:** Percentage overweight **Diet measures:** Not measured **Physical activity measures:** Not measured **Wellbeing measures:** Not measured **Other measures:** Socioeconomic status **Follow-up periods:** 21, 60 and 120 months (after start of programme) **Method of analysis:** Analysis of variance with between-subject factors of cohort and a repeated measures within-subject factor	**Anthropometry results:** Mean change in percentage overweight at 5 years: Group 1: -11.2% Group 2: +2.7% Group 3: +7.9% Mean change in percentage overweight at 10 years: Group 1: -7.5% Group 2: +4.5% Group 3: +14.3% **Attrition:** 8/75 attendees (11%) dropped out at 5 years 12/67 attendees (18%) dropped out at 10 years	**Limitations identified by authors:** Participants were all part of 'intact' families and most middle-class and white Self-report of some follow-up measures
Author(s) and year: Golan and Crow 2004 **Location:** USA **Aim of study:** To compare a family-based childhood obesity treatment programme targeted	**Setting:** Childhood obesity research clinic at university **Participants:** 60 obese children **Inclusion:** Aged 6-11 years of age, greater than 20% overweight, both	**Intervention(s):** Group 1: Parent only - 12 month treatment including 4 weekly meetings, 4 biweekly, 6 once every 6 weeks and 5 sessions during the last 7 months Group 2: children only – 12 month treatment including 7 weekly	**Anthropometry measures:** Percentage overweight **Diet measures:** Not measured **Physical activity measures:** Not measured **Wellbeing measures:**	**Anthropometry results:** Mean change in percentage overweight at 12 months: Group 1: -14.6% Group 2: -8.43% Mean change in percentage overweight at 12 month follow-up: Group 1: -13.6% Group 2: 0.0%	**Limitations identified by authors:** No measure of parenting style Sample size was modest Parent-child group not included

at parents only with a control intervention where only children were targeted **Study design:** RCT	parents living at home **Exclusion:** Current psychiatric problem, children unwilling to undergo blood sampling,	meetings and 23 biweekly meetings **Control:** No 'non-intervention' control **Sample sizes:** Assessed for eligibility = 160 Randomised: 60 Group 1 = 30 Group 2 = 30	Not measured **Other measures:** Not measured **Follow-up periods:** 1, 2 and 7 years after the end of the programme **Method of analysis:** Analysis of variance with between-subject factors of cohort and a repeated measures within-subject factor	Mean change in percentage overweight at 24 month follow-up: Group 1: -15.0% Group 2: -2.9% Mean change in percentage overweight at 7 year follow-up: Group 1: -29% Group 2: -20.2% **Attrition:** Group 1: 1/30 attendees (3%) dropped out by the end of the intervention Group 2: 9/30 attendees (30%) dropped out by the end of the intervention	
Author(s) and year: Golan, Kaufman and Shahar 2006 **Location:** Israel **Aim of study:** To compare a family-based childhood obesity treatment programme targeted at parents only with a control intervention where parents and children were targeted together **Study design:** RCT	**Setting:** Childhood obesity research clinic at university **Participants:** 60 obese children **Inclusion:** Aged 6-11 years of age, greater than 20% overweight **Exclusion:** Family member currently participating in a weight-loss programme, restrictions for either parents or children in taking part in a physical activity	**Intervention(s):** 6 month treatment including 10 weekly meetings, 4 biweekly and 2 monthly. In addition, 6 individual appointments were held once per month for each family. **Control:** Parent and child together group **Sample sizes:** Assessed for eligibility = 102 Randomised: 32 Parent only = 17 Parent and child = 20	**Anthropometry measures:** Percentage overweight BMI z score **Diet measures:** Family eating and activity habits questionnaire **Physical activity measures:** Family eating and activity habits questionnaire **Wellbeing measures:** Not measured **Other measures:** Parental authority questionnaire used to	**Anthropometry results:** Mean change in percentage overweight at end of intervention: Parent only: -9.5% Parent and child: -2.4% Mean change in BMI z score at end of intervention: Parent only: 0.4 Parent and child: 0.1 Difference between groups for both above measures was significant; p=0.02 and p=0.024 respectively. Mean change in percentage overweight at 12 month follow-up: Parent only: -12% Parent and child: -0.4%	**Limitations identified by authors:** The lack of a third condition where parents and children are targeted separately. The difference in refusal rates between the groups.

	programme, diagnosis of psychiatric or major endocrine pathology		measure parenting style **Follow-up periods:** 12 months after the end of the programme **Method of analysis:** Repeated measures ANOVA with treatment group as the between factor and time as the within factor.	Mean change in BMI z score at 12 month follow-up: Parent only: 0.4 Parent and child: 0.1 Difference between groups for both above measures was significant; p=0.045 and p=0.025 respectively. **Attrition:** Parent only: 2/17 attendees (12%) refused to participate Parent and child: 1/20 (5%) refused to participate	
Author(s) and year: Israel, Stolmaker and Andrian 1985 **Location:** USA **Aim of study:** To evaluate the effect of additional training in general child management skills in a behavioural treatment programme for overweight children **Study design:** RCT	**Setting:** Childhood obesity research clinic at university **Participants:** 33 obese children **Inclusion:** Aged 8-12 years of age, greater than 20% overweight, medical clearance from a physician **Exclusion:** None given	**Intervention(s):** Weight reduction only (WRO): 9 weekly 90 minute multicomponent behavioural weight reduction programme Weight reduction plus parent training (PT): 9 weekly 90 minute multicomponent behavioural weight reduction programme preceded by a short course for the parents in general child management skills **Control:** Waiting list control **Sample sizes:** Assessed for eligibility = 33	**Anthropometry measures:** Percentage overweight **Diet measures:** Eating Habit Checklist **Physical activity measures:** Not measured **Wellbeing measures:** Not measured **Other measures:** Knowledge of Behavioural Principles as Applied to Children **Follow-up periods:** 12 months after the end of the programme **Method of analysis:**	**Anthropometry results:** Mean change in percentage overweight at end of intervention: Both treatment groups = 15.15% p<0.001 Two treatment groups did not differ from each other **Attrition:** 3 families dropped out of the programme 7 families dropped out during the follow-up period	**Limitations identified by authors:** Study did not evaluate changes in child management behaviour. Limitations of the Eating Habit Checklist

		Randomised: 33 WRO = 12 PT = 12 Control = 9	Analysis of variance with between-subject factors of cohort and a repeated measures within-subject factor		
Author(s) and year: Nemet, Barkan, Epstein, Friedland, Kowen and Eliakim 2005 **Location:** Israel **Aim of study:** To examine the short and long term effects of a 3 month multi-component intervention on obese children **Study design:** RCT	**Setting:** Childhood obesity research clinic at university hospital **Participants:** 54 obese children **Inclusion:** Aged 6-16 years of age, medical clearance from a physician **Exclusion:** Organic cause for obesity, on medication that might interfere with growth or weight control	**Intervention(s):** 3 month programme including 4 lectures, 6 appointments with dieticians and twice-weekly physical activity training programme Control: One nutritional consultation and instructed to perform physical activity 3 times per week **Control:** Waiting list control **Sample sizes:** Assessed for eligibility = 54 Randomised: 54 Intervention = 30 Control = 24	**Anthropometry measures:** Body weight BMI Body fat percentage **Diet measures:** 2 day food record **Physical activity measures:** Physical activity questionnaire Progressive treadmill exercise test **Wellbeing measures:** Not measured **Other measures:** Serum lipid levels **Follow-up periods:** 12 months after the end of the programme **Method of analysis:** Analysis of variance with between-subject factors of cohort and a repeated measures within-subject factor	**Anthropometry results:** After 3 month intervention (intervention v. control): Change in body weight: -2.8kg v. 1.2kg Change in BMI: -1.7 v. -0.2 Significant changes ($p<0.05$) comparing intervention v control: **Attrition:** 6/30 attendees (20%) withdrew from the programme 2/24 control (8%) subjects completed the 3 month evaluation	**Limitations identified by authors:** Subjectivity of food recording technique Refusal of many participants to undergo blood sampling

Appendix 2 Evidence table for studies discussed in chapter 4 section 4.4

Author(s) and year: Bryant, Farrin, Christie, Jebb, Cooper and Rudolf 2011 **Location:** UK **Aim of study:** To carry out a feasibility trial of the WATCH IT community based intervention **Study design:** RCT	**Setting:** Community venue **Participants:** 70 obese children **Inclusion:** Aged 8-16 years of age, BMI > 98th percentile, parent and carer with fluent spoken English **Exclusion:** Medical cause for obesity, severe learning difficulties, significant medical or psychiatric problems, on medication that might interfere with growth or weight control	**Intervention(s):** 4 month programme using a motivation enhancing, solution focussed approach with optional extension of 4 or 8 months. Weekly individual appointments for families followed by a group physical activity session. **Control:** 12 month waiting list control **Sample sizes:** Assessed for eligibility = 96 Randomised: 70 Intervention = 35 Control = 35	**Anthropometry measures:** BMI Waist circumference Body fat **Diet measures:** WATCH IT diet questionnaire Home food availability checklist Dutch eating behaviour questionnaire **Physical activity measures:** Fitness (step test) 7 day physical activity by accelerometry Physical activity questionnaire for children (PAQ-C) Robinson school-based sedentary behaviour questionnaire **Wellbeing measures:** Pediatric quality of life Strengths and difficulties questionnaire Harter scale of perceived social and cognitive competence **Other measures:** 2 hour oral glucose tolerance Lipid levels Liver function assay	**Anthropometry results:** Mean change in BMI z score 12 months post baseline: Intervention: 0.03 (95% CI -0.05 to 0.11) Control: -0.03 (-0.12 to 0.06) Mean change in percent body fat 12 months post baseline: Intervention: 1.40 (0.31 to 2.38) Control: 0.20 (-1.41 to 1.72) **Attrition:** 5/35 attendees (14%) withdrew from the programme prior to the 6 month review 9/35 control participants (26%) withdrew from the group prior to the 6 month review	**Limitations identified by authors:** Study was underpowered Majority of families were of white, British nationality Intervention start date did not always did not always immediately follow baseline assessment Feasibility trial only conducted at one centre

			Blood pressure Parental height and weight **Follow-up periods:** 6 and 12 months post-baseline **Method of analysis:** Means with 95% CI for primary outcomes and standardised response means for questionnaires. Authors' stress trial not powered to assess effectiveness). BMI and waist circumference converted to SDS using UK 1990 growth references		
Author(s) and year: Coppins, Margetts, Brown, Garrett and Huelin 2011 **Location:** UK **Aim of study:** To determine if a multi-component family focused education package is more effective than a waiting list control group in treating childhood obesity **Study design:** Quasi-RCT	**Setting:** Schools **Participants:** 65 overweight and obese children **Inclusion:** Aged 6-14 years of age, BMI > 91st centile **Exclusion:** Intellectual disability which means they are unable to take part in activities, medical conditions which might impede physical activity	**Intervention(s):** Two Saturday workshops (total 8 hrs) 1–2 weeks apart; twice weekly 1-hour physical activity sessions during term time. Siblings aged 6–14 years and parents/ guardians encouraged to participate **Control:** Waiting list control (WLC) – 1 year delay **Sample sizes:** Assessed for eligibility = 65 Randomised: 65 I/C = 35	**Anthropometry measures:** BMI z score Waist circumference Body fat **Diet measures:** 7 day food diary **Physical activity measures:** 7 day activity diary **Wellbeing measures:** Not measured **Other measures:** Not measured **Follow-up periods:**	**Anthropometry results:** Over 2 years BMI z score fell significantly in intervention but not in WLC. Unadjusted between group difference = 0.3 ((95% CI) -0.62 to 0.02, P=0.06) <u>Unadjusted</u> Intervention: BMI z score: 0-12 months -0.17 (-0.26 to -0.08); 12-24 months -0.23 (-0.45 to -0.02); 0-24 months -0.44 (-0.7 to – 0.18) WLC= BMI z score: 0-12 months -0.08 (-0.24 to 0.07); 12-24 months -0.14 (-0.29 to 0.01); 0-24 months -0.14 (-0.35 to – 0.06)	**Limitations identified by authors:** Study was underpowered Children did not participate in the activity sessions as much as expected A waiting list control may not have been appropriate. There were a higher percentage of self referrals in the I/C group (60% v 36.7%). Under reporting in food diaries

		C/I = 30	6, 12, 18 and 24 months **Method of analysis:** ANOVA with adjustment for baseline measures	<u>Adjusted</u> (for baseline measures of age, weight, height, sum at skinfolds, referral source and gender) Intervention: BMI z score: 0-12 months - 0.13 (-0.26 to -0.008); 12-24 months 0.21 (-0.45 to -0.021); 0-24 months -0.41 (-0.71 to -0.11) WLC = BMI z score: 0-12 months -0.14(0.28 to -0.001); 12-24 months -0.14 (-0.35 to -0.079); 0-24 months 0.16 (-0.43 to 0.11) **Attrition:** At 6, 12 and 24 months respectively I: 11%, 20%, 40% WLC: 10%, 17%, 23%	
Author(s) and year: Croker, Viner, Nicholls, Haroun, Chadwick, Edwards, Wells and Wardle 2011 **Location:** UK **Aim of study:** To examine the acceptability and effectiveness of 'family-based behavioural treatment' (FBBT) for childhood obesity in an ethnically and	**Setting:** Hospital **Participants:** 72 obese children **Inclusion:** Aged 8-12 years of age, BMI > 91st centile, parent and child have a good command of English, at least one parent/guardian willing to participate in treatment **Exclusion:** Medical cause for	**Intervention(s):** 6 month FBBT comprising 10 weekly sessions, 3 fortnightly and 2 monthly sessions (approx. 1.5 hours each) **Control:** 6 month waiting list control group **Sample sizes:** Assessed for eligibility = 99 Randomised: 72 Intervention = 37 Control = 35	**Anthropometry measures:** BMI BMI z score Post-treatment %BMI **Diet measures:** Not measured **Physical activity measures:** Not measured **Wellbeing measures:** Self-perception profile for children Children's depression inventory Strengths and difficulties	**Anthropometry results:** No significant between-group differences for the primary outcome measures of BMI z-score and BMI from baseline to 6-months Both groups showed a significant (p=0.01) reduction in BMI z-score at the end of the 6-month period: Intervention: -0.11±0.16 Control: -0.10±1.6 No overall change in BMI or BMI z scores from 0–12 months for treatment group For those with follow-up to 12	**Limitations identified by authors:** High attrition rate. Some missing baseline data. ITT analyses for 6-month data only. No 12-month data for control group Not possible to blind families or researchers to group allocation

socially diverse sample of families in a UK National Health Service (NHS) setting **Study design:** RCT	obesity, type 2 diabetes, taking obesity medication, undergoing obesity treatment, significant learning difficulties, significant mental health problems in child or parent		questionnaire Pediatric quality of life inventory Children's eating attitudes test **Other measures:** Blood pressure Pubertal status **Follow-up periods:** 12 months after the end of the intervention for treatment group completers **Method of analysis:** Independent t-tests or Mann–Whitney tests (continuous variables) or w2-tests (categorical variables). All 6-month outcomes analysed on an ITT basis (n=60) tested for normality using Kolmogorov–Smirnov tests and transformations were performed as appropriate. MANCOVA to test group differences for parametric data. Paired t-tests or Wilcoxon signed-rank tests to examine within-group changes over the intervention	months: Baseline = 3.14±0.72 6 months = 2.98±0.75 12 months = 3.03±0.78 **Attrition:** 15/37 attendees (41%) withdrew from the programme prior to the 6 month review 16/35 control participants (46%) withdrew from the group prior to the 6 month review	
Author(s) and year: Golley, Magarey, Baur, Steinbeck and	**Setting:** Hospital	**Intervention(s):** P+DA: Parenting-skills training + intensive	**Anthropometry measures:** BMI z score	**Anthropometry results:** At 12 months BMI z score: P+DA: reduced by 9% (range -	**Limitations identified by authors:**

Daniels 2007 **Location:** Australia **Aim of study:** To evaluate the relative effectiveness of parenting-skills training as a key strategy for the treatment of overweight children **Study design:** RCT	**Participants:** 111 overweight children **Inclusion:** Aged 6-9 years fo age, BMI > 91st centile, Tanner stage 1, caregiver willing to attend sessions, care giver able to read and understand English **Exclusion:** BMI z score > 3.5; diagnosed with a syndromal cause of obesity; using medications that influence weight gain or loss; diagnosis of physical or developmental disability or chronic illness; sibling enrolled in the study	lifestyle education: Triple P Positive Parenting Programme. 4 weekly 2-hour sessions, then 4 weekly, followed by 3 monthly 15-20 minute individual telephone sessions. Triple P Programme followed by 7 intensive lifestyle support group sessions General 'healthy lifestyle' pamphlet P: Parenting-skills only: Triple P Programme and pamphlet **Control:** Wait list control (WLC): Healthy lifestyle pamphlet only - telephone contact during 12 month wait list period as retention strategy **Sample sizes:** Assessed for eligibility = 262 Randomised: 111 P+DA = 38 P = 37 WLC = 36	Waist circumference z score **Diet measures:** Food intake via validated 54-item parent completed dietary questionnaire **Physical activity measures:** Parent-reported 20-item activity questionnaire **Wellbeing measures:** Not measured **Other measures:** Metabolic health outcomes - cholesterol, triacyglycerol, blood pressure, glucose, insulin **Follow-up periods:** 6 months (programme completion) and 12 months **Method of analysis:** Means±SD and proportions. chi-squared to explore effect of baseline measures weight status, parental weight status, ethnicity, age,SES. Baseline differences between those who did and did not attend follow up explored by t tests.	85 to 18%) P: reduced by 6% (-48% to 49%) WLC: reduced by 5% (-78% to 16%) No statistically significant difference between groups Absolute differences: P+DA: -0.24±0.43 P: -0.15±0.47 WLC: -0.13±0.40 Waist circumference z score fell significantly over 12 months in both intervention groups but not WLC group. Absolute differences: P+DA: -0.31±0.53 P: -0.17±0.0.50 WLC: -0.02±0.58 **Attrition:** 24% at 6 months (post-treatment) and 20% at 12 months Programme attendance did not differ between the two groups	Study power Intervention adherence and dilution of effect size with ITT procedures may have prevented a statistically significant result

			Secondary analyses with gender as a factor and per protocol analysis for families attending ≥75% of the sessions		
Author(s) and year: Hughes, Stewart, Chapple, McColl, Donaldson, Kelnar, Zabihollah, Ahmed and Reilly 2008 **Location:** UK **Aim of study:** To compare a generalisable best-practice individualised behavioural intervention with standard dietetic care among overweight children **Study design:** RCT	**Setting:** Hospital outpatient **Participants:** 134 obese children **Inclusion:** Aged 5-11 years of age, BMI > 98th centile, attending a standard elementary school, at least 1 parent who perceived the child's weight as a problem and was willing to make lifestyle changes **Exclusion:** Underlying medical cause for overweight, serious comorbidity requiring urgent treatment, had received treatment for overweight in the past year	**Intervention(s):** 6 month intervention comprising 8 appointments appointments (7 out-patient, 1 home visit) over 26 weeks with 5 hours contact time **Control:** Standard dietetic care for overweight individual; 3-4 outpatient appointments over 6 to 10 months with total contact time of about 1.5 hours **Sample sizes:** Assessed for eligibility = 237 Randomised: 134 Intervention = 69 Control = 65	**Anthropometry measures:** BMI z score **Diet measures:** Not measured **Physical activity measures:** 7 day accelerometer diary **Wellbeing measures:** Pediatric quality of life inventory **Other measures:** Socioeconomic status Deprivation category **Follow-up periods:** 6 and 12 months after baseline **Method of analysis:** Group differences using Mann-Whitney test or Chi-squared tests. Intention to treat involving all who attended follow-up (no imputation for missing data). Per-Protocol using participants who	**Anthropometry results:** No between group differences in BMI z score using both ITT and per protocol analyses. Median difference at 6 and 12 months (ITT analysis) was 0.03 (-0.05 to 0.11) and -0.04 (-0.17 to 0.07) respectively Both groups showed a significant reduction in BMI z score at the end of the 6-month period: Intervention: -0.10 (-0.24 to -0.02) Control: -0.06 (-0.22 to 0.05) Both groups showed a significant reduction in BMI z-score at the end of the 12-month period: Intervention: -0.07 (-0.32 to 0.04) Control: -0.19 (-0.31 to 0.02) **Attrition:** 20/69 attendees (29%) withdrew from the programme prior to the 6 month review 17/65 control participants (26%) withdrew from the group prior to the 6 month review	**Limitations identified by authors:** Lacks a no treatment control group Being on a waiting lists and being 'identified' may motivate people to make changes. Chosen children very overweight (BMI z score >3) and may have been resistant to treatment

			attended ≥75% of scheduled appointments		
Author(s) and year: Janicke, Sallinen, Perri, Lutes, Huerta, Silverstein and Brumback 2008 **Location:** USA **Aim of study:** To assess the effectiveness of parent-only vs family-based interventions for pediatric weight-management in underserved rural settings. Project STORY **Study design:** RCT	**Setting:** Community. Cooperative Extension Service offices **Participants:** 93 overweight or obese children **Inclusion:** Aged 8-14 years of age, BMI >85th centile; physician approval to join study **Exclusion:** Child or parent had medical condition contraindicating mild energy restriction or moderate physical activity; use of prescription weight-loss drugs; enrolled in another weight loss programme	**Intervention(s):** FB: Behavioural family-based. Weekly group sessions (90 mins) for 8 weeks, then bi-weekly for 8 weeks (24 weeks total) PO: Behavioural parent-only. Emphasis on activity targets to work with children to achieve goals **Control:** Waiting list control (WLC) **Sample sizes:** Assessed for eligibility = 111 Randomised: 64 FB = 33 PO = 34 WLC = 26	**Anthropometry measures:** BMI z score Parental BMI **Diet measures:** Child caloric intake **Physical activity measures:** Not measured **Wellbeing measures:** Not measured **Other measures:** Not measured **Follow-up periods:** 10 months from baseline **Method of analysis:** ITT used. Analysis of covariance (ANCOVA)	**Anthropometry results:** At 4 months, PO vs WLC demonstrated greater decrease in BMI z score (mean difference 0.127; 95% CI 0.027 to 0.226) No significant difference between family-based and control condition (0.065; 95% CI -0.027 to 0.158) At 10 months, PO and FB had greater decreases compared to baseline than the WLC; Mean differences in BMI z score = 0.115 (95% CI 0.003 to 0.220) and 0.136 (95% CI 0.018 to 0.254)respectively No difference between the PO and FB groups at either time point **Attrition:** 81/93 attendees (13%) completed 71/93 (24%) attended for 10 month follow up	**Limitations identified by authors:** Clinical significance of findings unclear. Measures of physical activity and dietary intake not objective. Measures of satisfaction with the study not derived from children in PO condition. Median income of intervention families, below national averages, but higher than that commonly seen in rural communities. Unlike other FB interventions parents did not experience significant decreases in weight status
Author(s) and year: Kalavainen, Korppi and Nuutinen 2007 Kalavainen, Korppi and Nuutinen 2011 **Location:** Finland	**Setting:** Health centres and outpatient clinics **Participants:** 70 obese children **Inclusion:** Aged 7-9 years of	**Intervention(s):** 15 sessions of 90 min duration held separately for parents and children, except one session on making healthy snacks **Control:** Treatment modified from	**Anthropometry measures:** Weight for height (based on Finnish national growth charts) BMI BMI z score **Diet measures:**	**Anthropometry results:** There were no significant differences between the treatment arms in the changes of outcome measures from baseline to 2- or 3-years follow-up visits Intervention group lost more	**Limitations identified by authors:** Results not generaliseable as families more aware and motivated than would be typical across population.

Aim of study: To compare the efficacy of group treatment stressing a health-promoting lifestyle with routine counselling in the treatment of childhood obesity **Study design:** RCT	age, the presence of weight for height from 120 to 200% **Exclusion:** Disease or a medication causing obesity; obvious movement disturbance; major mental problems in either children or parents, family member participating in alternative weight management program	current counselling practice for obese children in Finnish school health care. Two appointments for each child with school nurses and booklets families with info on weight management, eating habits and physical activities **Sample sizes:** Assessed for eligibility = 83 Randomised: 70 Intervention = 35 Control = 35	Not measured **Physical activity measures:** Not measured **Wellbeing measures:** Not measured **Other measures:** Not measured **Follow-up periods:** 6, 18 and 30 months post-intervention **Method of analysis:** Univariate analyses with independent samples t-tests for continuous variables and χ^2 test or Fisher's exact test for discrete variables. MANOVA for continuous variables. Logistic regression analysis. Correlation of change in weight for height with change in BMI and BMI-SDS evaluated using Pearson's linear correlation coefficients	weight for height (6.8%) than control (1.8%) (P=0.001) Change in BMI z score: End of treatment: intervention = -0.3±0.3, control = -0.2±0.3, p=0.022 6 month follow-up: intervention = -0.2±0.3, control = -0.1±0.3, p=0.081 18 month follow-up: intervention = -0.2±0.3, control = -0.2±0.4, p=0.840 30 month follow-up: intervention = -0.3±0.4, control = -0.3±0.6, p=0.916 **Attrition:** The attrition rate <3%. 69/70 at 6 and 18 months 68/70 at 30 month	Sample size not achieved. Weight and height measured at inconsistent times throughout day. Lack of no intervention control group. Data on pubertal status not registered during follow-up
Author(s) and year: Magarey, Perry, Baur, Steinbeck, Sawyer, Hills, Wilson, Lee and Daniels 2011 **Location:**	**Setting:** Children's Hospital and medical centre **Participants:** 169 overweight children	**Intervention(s):** P+HL: Parenting skills with healthy lifestyle Twelve 90-120-minute group sessions (open to both parents but usually attended by mothers) and 4 telephone	**Anthropometry measures:** BMI z score Waist circumference z score **Diet measures:** Not measured	**Anthropometry results:** At 24-months overall reductions in BMI z score (0.26, 95% CI 0.22 to 0.30) and waist z score (0.33, 0.26 to 0.40) across both groups but no significant between group differences	**Limitations identified by authors:** Lack of group difference may be attributable to the generic (rather than obesity specific)

Australia **Aim of study:** To evaluate a healthy lifestyle intervention to reduce adiposity in children aged 5-9 years and assess whether adding parenting skills training would enhance this effect **Study design:** RCT	**Inclusion:** Aged 5-9 years of age, BMI > 91st centile, pre-pubertal, caregiver willing to attend sessions and able to speak English **Exclusion:** BMI z score >4.0; a syndromal cause of obesity; using medications that influence weight; physical or developmental disability; chronic illness; sibling enrolled in the study	sessions over 6 months tapered (weekly, bimonthly, then monthly). During parental sessions, children attended optional (physically) active child care **Control:** HL: Healthy lifestyle programme only Eight 90-120-minute group sessions (open to both parents but usually attended by mothers) and 4 telephone sessions over 6 months tapered (weekly, bimonthly, then monthly). During parental sessions, children attended optional (physically) active child care **Sample sizes:** Assessed for eligibility = 237 Randomised: 169 P+HL = 85 HL = 84	**Physical activity measures:** Not measured **Wellbeing measures:** Programme impact via the Parenting Sense of Competence Scale Alabama Parenting Questionnaire **Other measures:** Not measured **Follow-up periods:** 12, 18 and 24 months post-baseline **Method of analysis:** Means ± SD and proportions for normally distributed variables. Linear mixed models to explore effects of time, group, gender, site. ITT analysis used and second per protocol analysis of only those who attended 75% or more of program sessions	10% reduction in z scores from baseline to 6 months (end of intervention) was maintained to 24-months with no additional intervention **Attrition:** Post-intervention (6 months), 12 months and 24 months respectively: P+HL: 22.4%, 30.6%, 38.8% HL: 16.7%, 23.8%, 35.7%	nature of the intervention
Author(s) and year: McCallum, Wake, Gerner, Baur, Gibbons, Gold, Gunn, Harris, Naughton, Riess,	**Setting:** General medical practice **Participants:** 163 overweight or	**Intervention(s):** Four standard consultations with GP over 12 weeks. A 'solution focused' approach to set and	**Anthropometry measures:** BMI BMI z score **Diet measures:**	**Anthropometry results:** BMI z score: No significant difference. At 9 months unadjusted difference (I-C) 0.04 (95% CI: -0.16 to 0.23) and adjusted	**Limitations identified by authors:** Dose of intervention may have been too low, more sessions

Sanci, Sheehan, Ukoumunne and Waters 2007 **Location:** Australia **Aim of study:** To evaluate the Live, Eat and Play (LEAP) trial to reduce gain in body mass index (BMI) in overweight / mildly obese children in the primary care setting **Study design:** RCT nested within a baseline cross-sectional BMI survey	obese children **Inclusion:** Aged 5-9 years of age, classified as overweight / mildly obese according to the IOTF cut-off points, not receiving ongoing weight management in secondary or tertiary care, parents provided contact details **Exclusion:** Chromosomal, endocrine or medical condition / disability / medication that could impact on weight or growth, very obese children (BMI z score > 3)	record lifestyle goals targeting change in nutrition, physical activity, and sedentary behaviour, supported by purpose designed family materials in form of personalised 20 page family folder **Control:** No intervention [GP records audited to assess any contamination] **Sample sizes:** Assessed for eligibility = 505 Randomised: 163 I = 82 C = 81	4 day parent reported child food diary **Physical activity measures:** 4 day parent reported child activity diary **Wellbeing measures:** PedsQL (parent proxy) PedsQL (child self-report Body satisfaction (Collins body figure perception) Physical appearance and self-worth (modified Harter scale) **Other measures:** Not measured **Follow-up periods:** 9 and 15 months post-randomisation **Method of analysis:** Mean differences (with 95% CI and p values) adjusted for age, sex and socio-economic status (based on the Australian Bureau of Statistics Socio-Economic Indexes for Areas, SEIFA)	difference (I-C)-0.09 (95%CI: -0.20 to 0.02) At 15 months unadjusted difference (I-C) 0.08 (95% CI: -0.12 to 0.29) and adjusted difference (I-C) -0.03 (95%CI: -0.17 to 0.1) **Attrition:** At randomisation: 3/82 (I) At 9 month follow-up: I: 9/79 C: 1/81 At 15 months follow-up: I: 3/73 C: 4/80	may be needed. Solution focused approach may have lead to goals that were not addressing BMI. Lack of quality control on GP consultations, no objective monitoring of GP consultation
Author(s) and year: Okely, Collins, Morgan, Jones, Warren, Cliff, Burrows, Colyvas,	**Setting:** Childhood obesity research clinic at university	**Intervention(s):** 6 month programme including 3 intervention groups:	**Anthropometry measures:** BMI z score Waist circumference	**Anthropometry results:** All 3 groups reduced BMI z-score at 6 months, and reductions were maintained at 12 months.	**Limitations identified by authors:** No assessment of parenting behaviours

Steele and Baur 2010 Collins, Okely, Morgan, Jones, Burrows, Cliff, Colyvas, Warren, Steele and Baur 2011 **Location:** Australia **Aim of study:** To compare a child centred physical activity programme with a parent centred dietary modification programme **Study design:** RCT	**Participants:** 165 overweight children **Inclusion:** Aged 5.5 to 9.9 years, overweight or obese, prepubertal (Tanner Stage I), generally healthy **Exclusion:** Extreme obesity (BMI z score > 4), syndromal obesity, following therapeutic diet, chronic illness, taking medication associated with weight change, significant dietary restrictions	DIET: parent-centred dietary modification programme PA: child-centred physical activity skill development programme PA+DIET: combination of the parent centred dietary modification and the child centred physical activity skill development programme Each intervention comprised 10 weekly 2-hour face-to-face sessions; homework activities; 3-month relapse prevention program **Control:** No 'non-intervention' control **Sample sizes:** Assessed for eligibility = 505 Randomised: 206 DIET = 63 PA = 73 PA+DIET = 70	**Diet measures:** The Australian Child and Adolescent Eating Survey **Physical activity measures:** Fundamental movement skill proficiency Physical activity was measured for eight consecutive days using accelerometers Time spent in sedentary activities Sit-to-stand proficiency **Wellbeing measures:** Health-related quality of life **Other measures:** Change in metabolic profile (blood pressure, fasting total cholesterol levels, HDL and LDL cholesterol, triglycerides, glucose, insulin and C-reactive protein) **Follow-up periods:** 12 and 24 months after the end of the programme **Method of analysis:** Linear mixed models to assess all outcomes for the impact of group, time, and the group-by-	Mean (95% CI) reduction in BMI z-score at 6 months from baseline was: DIET: -0.31 (-0.39 to -0.22) PA: -0.16 (-0.24 to -0.09) PA+DIET: -0.31 (-0.38 to -0.24) Mean (95% CI) reduction in BMI z-score at 12 months from baseline was: DIET: -0.39 (-0.51 to -0.27) PA: -0.17 (-0.28 to -0.06) PA+DIET: -0.32 (-0.42 to -0.22) Mean (95% CI) reduction in BMI z-score at 24 months from baseline was: DIET: -0.35 (-0.48 to -0.22) PA: -0.19 (-0.30 to -0.07) PA+DIET: -0.24 (-0.35 to -0.13) Compared with the PA group, participants in the DIET group and the PA+DIET group had a greater reduction in BMI z-score (p=0.02) There was a group-by-time difference in BMI *z*-score (adjusted for gender) at 24 months (p=0.04), with the greatest difference being the reduction for the DIET group compared with the PA group **Attrition:** Intervention retention rates: DIET = 67% PA = 86% PA+DIET: 86%	Did not include a no treatment control group Lower than expected sample size Wide confidence intervals for some of the secondary outcomes High dropout rates Results may not be generaliseable to those from other socioeconomic groups. Activity programme may not be generaliseable to those outside the age range in study

			time interaction. Adjusted models contained any additional significant effects due to main effects and two-way interactions between base model terms of sex, site, and age. Mixed models were fitted by use of SAS. Kenward-Roger adjustment for downward bias in the variance-covariance matrix. Differences of means and 95% confidence intervals	12 month retention rates: DIET = 71% PA = 52% PA+DIET = 72% 24 month retention rates: DIET = 52% PA = 56% PA+DIET = 60%	
Author(s) and year: Sacher, Kolotourou, Chadwick, Cole, Lawson, Lucas and Singhal 2010 **Location:** UK **Aim of study:** To evaluate the effectiveness of the Mind, Exercise, Nutrition, Do it (MEND) Program, a multi-component community-based childhood obesity intervention **Study design:** RCT	**Setting:** Sports centres and schools **Participants:** 116 obese children **Inclusion:** Aged 8-12 years of age, BMI > 98th centile, no apparent clinical problems, at least one parent or carer able to attend with the child **Exclusion:** Comorbidities, physical disabilities, learning difficulties	**Intervention(s):** 6 month intervention comprised 18 sessions delivered over 9 weeks followed by a 12 week free family swim pass **Control:** 6 month waiting list control **Sample sizes:** Assessed for eligibility = 117 Randomised: 116 Intervention = 60 Control = 56	**Anthropometry measures:** BMI Waist circumference % body fat **Diet measures:** Not measured **Physical activity measures:** Cardiovascular fitness (step test) Physical activity questionnaire **Wellbeing measures:** Self-perception profile for children **Other measures:** Body composition Socio economic status	**Anthropometry results:** Participants in the intervention group had a reduced BMI z-score (−0.24; P < 0.0001) and reduced waist circumference z-score (−0.37; P < 0.0001) at 6 months when compared to the controls At 12 months, children in the intervention group had reduced their BMI z-scores 0.23 (P < 0.0001) and waist z score by 0.47 (P < 0.0001) **Attrition:** 23/60 attendees (38%) withdrew from the programme prior to the 6 month review 11/56 control participants (20%) withdrew from the group prior to the 6 month review	**Limitations identified by authors:** Lack of blinding for measurement of outcomes High drop out at 6 months Relatively short follow up

			Follow-up periods: 12 months from baseline **Method of analysis:** Mean difference adjusted for baseline		
Author(s) and year: Savoye, Shaw, Dziura, Tamborlane, Rose, Guandalini, Goldberg-Gell, Burgert, Cali, Weiss and Caprio 2007 Savoye, Nowicka, Shaw, Yu, Dziura, Chavent, O'Malley, Serrecchia, Tamborlane and Caprio 2011 **Location:** USA **Aim of study:** To determine if beneficial effects of a weight management program could be sustained for up to 24 months **Study design:** RCT	**Setting:** School **Participants:** 209 overweight children **Inclusion:** Aged 8-16 years of age, BMI > 95th centile, English-speaking **Exclusion:** Serious medical conditions; use of medications that may cause weight gain/loss; involvement in existing weight management programme	**Intervention(s):** Intensive family-based lifestyle program of exercise, nutrition and behaviour modification. Twice-weekly sessions for 6 months, then twice monthly for further 6 months Intervention group further randomized 1:1 to Structured Meal Plan (n=35) or Better Food Choices group (n=105), but this randomization discontinued due to high dropout rate. Only results for Control and Better Food Choices groups analysed **Control:** Traditional clinical weight management counselling every 6 months **Sample sizes:** Assessed for eligibility = 284 Randomised: 209 Intervention = 140 Control = 69	**Anthropometry measures:** BMI z score BMI Body mass % body fat Fat mass **Diet measures:** Not measured **Physical activity measures:** Not measured **Wellbeing measures:** Not measured **Other measures:** Triglycerides, cholesterol, blood pressure, fasting insulin and glucose, insulin resistance (data not extracted) **Follow-up periods:** 24 months post-baseline **Method of analysis:** Mean changes from baseline and 95% confidence intervals (CIs)	**Anthropometry results:** Treatment effect was sustained at 24 months in the intervention versus control group for BMI z score (-0.16 95% CI -0.23 to -0.09) At 6 months mean change in BMI z score, 95% CI: I = -0.16 (-0.20 to -0.13) C = 0.01 (-0.04 to 0.06) Treatment effect (I-C) mean = -0.18, -0.24 to -0.12). P-Value <0.001 At 12 months mean change in BMI z score, 95% CI: I = -0.21 (-0.25 to -0.17) C = 0.01 (-0.04 to 0.07) Treatment effect (I-C) mean = -0.23, -0.29 to -0.16). P-Value <0.001 At 24 months: mean change in BMI z score, 95% CI: I = -0.20 (-0.25 to -0.16) C = -0.05 (-0.10 to 0.01) Treatment effect (I-C) mean = -0.16, -0.23 to -0.19). P-Value <0.001 **Attrition:** At 6, 12 and 24 months respectively:	**Limitations identified by authors:** High attrition, though dropout rates were similar in both treatment groups Lack of psychosocial measures Cost-effectiveness information

				Intervention: 18%, 29%, 57% Control: 29%, 36% and 55%	
Author(s) and year: West, Sanders, Cleghorn and Davies 2010 **Location:** Australia **Aim of study:** To evaluate the effects of the Group Lifestyle Triple P intervention on parenting and child weight-related behaviour **Study design:** RCT	**Setting:** Clinic, teaching hospital and schools **Participants:** 101 overweight children **Inclusion:** Aged 4-11 years of age, parent described the child's body size as overweight, parent agreed to attend 12 week intervention **Exclusion:** Use of medications that may cause weight gain/loss; child has a severe developmental delay or disability	**Intervention(s):** Group Lifestyle Triple P – 12 week programme delivered to parents only. Consists of nine 90 minute group sessions and three 20 minute telephone calls. **Control:** 12 week waiting list control group **Sample sizes:** Assessed for eligibility = 205 Randomised: 101 Intervention = 52 Control = 49	**Anthropometry measures:** BMI z score **Diet measures:** Not measured **Physical activity measures:** Not measured **Wellbeing measures:** Parenting self-efficacy **Other measures:** Weight-related problem behaviour Ineffective parenting Lifestyle Behaviour Checklist **Follow-up periods:** 12 months post-baseline **Method of analysis:** Two-way and one-way repeated measures MANOVA. All analyses used intention to treat procedures	**Anthropometry results:** Participants in the intervention group had a reduced BMI z-score (–0.11; P < 0.001) at 12 weeks when compared to the controls At 12 months, children in the intervention group had reduced their BMI z-scores -0.19 (P < 0.001) **Attrition:** 41/52 attendees (79%) withdrew from the programme prior to the post-assessment 34/52 attendees (65%) did not attend their 1 year assessment 3/49 control participants (6%) withdrew from the group prior to post-assessment	**Limitations identified by authors:** Difficult to compare results to previous studies due to differences in research design, intervention length, measures and reference population Families who participated were self-referred A single practitioner delivered all the intervention Sample were mainly white, well-educated parents with moderate levels of employment and income

Appendix 3 Research and development approval for the focus groups from Telford and Wrekin PCT

Telford and Wrekin NHS
Primary Care Trust

R & D Office
Sommerfeld House
Sommerfeld Road
Trench Lock
Telford
Shropshire TF1 5RY
Direct Telephone Number: 01952 265142

10 August 2005

RECEIVED
11 AUG 2005

Miss Helen Phillips
Researcher Childhood Obesity & Physical Activity
Telford & Wrekin PCT
The Davidson Suite,
The Health Centre
Wellington
Telford
TF1 1PZ

Dear Helen

Re: School – based focus groups regarding healthy lifestyles and choices

Thank you for sending me the documentation related to your research project.

I am pleased to inform you that we have now received and reviewed all necessary paperwork and are happy to give approval for this research to go ahead within Telford and Wrekin PCT. Details of your research will be held on our research and development database and if appropriate will be submitted to the National Research Register.

Your research is now covered by NHS indemnity as set out in HSG(96)48. You are required to notify the R&D Co-ordinator of any changes to the research protocol or research staff and to report any adverse events. We are interested and required to monitor the progress of the project and therefore ask that you inform us of the research outcomes. We will also be conducting an annual 10% audit of research projects held on our database and therefore may approach you in the future with regard to this.

The PCT wishes you every success in your research.

Yours sincerely

[redacted]

pp. **Dr Anthony Rathbone**
Research & Development Lead Manager

Enc. Research leaflet
cc Trish Hayward, R&D Co-ordinator

Appendix 4 Research and development approval for the focus groups from Coventry University

- 9 MAY 2006

Memorandum

Coventry University

Faculty of Health & Life Sciences

To Helen Pittson

Cc Orla Dunn

From
Lesley Watts
Research Manager

Extension 5985 **email** l.watts@coventry.ac.uk **Delivery Point** WF124

Our Reference
PG04a/06

Your Reference

Date
3rd May 06

Dear Helen,

Coventry University Ethics Committee

I am pleased to inform you that your application to Coventry University Ethics Committee has been successful, subject to the conditions listed in the Peer Review Form. Please ensure that you take note of these comments, and I would be grateful if you could return copies of the schools' permission letters to me.

Best wishes for your study.

Regards,

[redacted]

Lesley Watts
Secretary
Coventry University Ethics Committee
Tel. 024 7679 5945

Week 1 – Discussion Guide

Topic for week: Introduction / Ice Breakers / Health

Equipment Required:

Desk top flip chart
Flip chart pens
Post-it notes in different colours and sizes
'Nice to know you' blank sheets
'Nice to know you' questions
Pens
Felt-tip pens
Disposable cameras
Scrapbooks x 8
Spare paper
Glue

Aims: To introduce the focus groups to the pupils.
To establish a working agreement.
Facilitators to establish a rapport with participating pupils.
To create a team spirit within the group.
To begin to gain an insight into their views on health.
To use a number of qualitative techniques and assess their effectiveness.

Questioning Route:

Opening: *(Equipment required: flipchart paper, flipchart pens).*
(10 mins)

Facilitator and assistant facilitator introduce themselves; e.g.

Good morning. My name is *(facilitator)* and this is *(assistant facilitator)* I work for Telford and Wrekin Primary Care Trust which is the organisation which looks after the hospitals, doctors surgeries and lots of other things to do with health. Thanks for agreeing to take part in these groups. The groups are going to run for 4 weeks during your *(PSHE lessons/dinner times)*. Over the next 4 weeks we want to find out a little bit more about you and your views on topics like health, food and exercise. I hope it won't be like a lesson and we can use different activities to have some fun. You don't have to do or say anything you don't want to during the sessions. The information you give us going to be used to plan a healthy eating and physical activity programme for children and their families who

need some help and encouragement to live a healthier life. You have probably noticed the recorder in the middle of the table. This is going to record what we talk about. Don't feel embarrassed we're just using it so we capture everything you say.

To make our group work and make the next 4 weeks enjoyable we need to work as a team and to do that the first thing I would like us to do is to produce a working agreement that we can all follow. So this working agreement is going to be some rules or guidelines that we can all follow each week. If you shout out your ideas then I will write them on the flip-chart. What sort of guidelines do you think we should have? what do good teams do to work well together?

Facilitator to write ideas on the flip chart paper. May need to help them along with some ideas such as; have fun, work together, co-operate, be honest, respect each other, share thoughts, listen to each other, show interest. Try to instil a feeling of being a 'team'.

Ice-breaker: (10 mins) *(Equipment required: Nice to know you blank sheets, questions, pens).*

Nice to know you. (No need to run through everyone's answers but use it as a way to find out what everyone's name is).

Brainstorm: (1) (10 mins) *(Equipment required: flipchart paper, post-it notes, pens).*

Divide the flip-chart in 2 (vertically) and on post-it notes ask them to write things about their school they think are healthy. Talk through what they have written as they stick them on the flip-chart.

Emphasise that their handwriting and spelling doesn't matter.

Repeat; but ask them to write things on post-it notes that they think are unhealthy about their school.

Brainstorm: (2) (15 mins) *(Equipment required: flipchart paper, felt tip pens).*

Split the group so they are now working in 2's or 3's;
Give them a piece of flip-chart paper and ask them to split it into 2. On one side ask them to draw or write things THEY DO outside of school that are healthy, and on the other side things THEY DO outside of school which are unhealthy.

Allow the groups to talk through what they have drawn and written. Try to encourage each person from the group to say something – don't have a spokesperson. Encourage them to expand on what they have written.

(Equipment required: flipchart paper, flip chart pens).

Ask them; "what do you think the word 'health' means?"
"is it important for you to be healthy?"

Write the answers on the flipchart.

Ending: (5 mins) Give out the scrap books and invite them to stick their 'Nice Knowing you' in. Probably easier if you keep hold of the scrapbooks and bring them each week as they might be too big to put in their school bags. They can have them to keep at week 4.

Re-cap over session;
- working agreement
- things about school they think are healthy and unhealthy
- things they do which they think are healthy and unhealthy
- what 'health' means to them

Use the flip chart as a prompt and try to verbalise what you have heard from them.

Check with them that your re-cap is correct and that you haven't missed anything.

Explain that you will photograph everything they have done today, e.g. working agreement, ideas about why their school is healthy and unhealthy, and let them have it next week so they can stick it into their scrap books.

Hand out disposable cameras. Invite them to use them for the next week to use outside of school to take photos of the things they do, activities they take part in, maybe their favourite food, their family, etc. Things that they normally do in the week. Doesn't have to be all the things they enjoy doing! Bring the cameras back the following week and I will get them developed for the 4th week. They can keep the photos and negatives. We will just use them in a discussion.

It's a good idea to ask them to take the first photo of themselves so you can check they understand how to use the camera and then we know who each film belongs to.

After the group:

Write up observations and key points.

HP: Photograph the working agreement and the other activities for next week so each member of the group can have a copy to put into their scrapbook.

Week 2 – Discussion Guide

Topic for week: Food / Nutrition / Healthy eating

Equipment Required:

Desk top flip chart
Flip chart pens
Copies of activities from last week
Working agreement
Human Bingo blank sheets
4 sets of (9) magazine cuttings of food
Pens
Felt-tip pens
Spare paper
Glue
Scrapbooks

Aims: To find out what foods children think are healthy and unhealthy.
To investigate the group's perceptions of the effects of food and drink.
To gain an insight into the choices children feel they have.
To understand more about the barriers to children eating healthily.

Questioning Route:

Opening: (5 mins) *(Equipment required: working agreement, copies of activities, scrapbooks).*

Re-cap of working agreement.
Re-cap of what they did last week and what you as a facilitator heard – check they agree. Handout copies of the activities and allow them to stick them into their scrapbooks.
Collect in the disposable cameras.
Explain that today we are going to talk about food.

Ice-breaker: (5 mins) *(Equipment required: Human Bingo blank sheets, pens).*

Human Bingo. Set a time limit of 2 minutes and then see who has the most answers after this time.

24 hour recall activity: (5 mins) *(Equipment required: A4 paper, pens)*

Give out the 24 hour recall sheets. In the first column ask them to write everything they had to eat yesterday. In the second column write who

they ate that food with. In the third column write who chose what they ate.

e.g.

What did you eat?	Who did you eat with?	Who chose what you ate?

Ask:
How difficult is it to remember what you have eaten?
Who people eat with – when/where?
What factors influence their food choice?
How much choice they have over what they eat?

Food Sort Activity: (5 mins) *(Equipment required: magazine cuttings of food in sets of 9, flip-chart paper).*

(1) Work in pairs. Ask them to prioritise the 9 photographs of a range of healthy and unhealthy foods;
- Sort the photos from the healthiest to the unhealthiest (put them on a piece of flip-chart paper).
- Listen to how they are making their choice.
- Take a photo of each groups.

(10 mins) Ask them to talk through their choice (try to allow each person in each pair to put their thoughts across);
- Which food did the groups have as the most healthy/unhealthy?
- Why are the foods healthy/unhealthy?
- What happens when we eat unhealthy food?
- Why are healthy foods good for us?
- How much of different types of food should we eat? Try and go through examples of the food groups.

(2)

(10 mins) In pairs (but one individual goes at a time); sort the photos from what you like to eat most to what you dislike eating (take photos of each persons choice).
- Why do you like some foods – what do you like about it? Is it a healthy food?
- Why don't we always eat healthy foods?
- How important to you is it to eat healthy foods?
- What foods should you eat more of? Do you? Why or why not?
- Who chooses the food you eat? When – at home/at school?
- Where do you eat most of your meals?

Swap over and the other person in the pair does the same thing.

Drinks:

(10 mins) Question as a group.
What about drinks?
- What drinks do you have at school/at home?
- What drinks are better for us?
- Who chooses the drinks you have?
- How much should we drink each day

Ending: Re-cap over session;
(5 mins)
- foods they felt were healthy/unhealthy.
- amounts of foods we should eat.
- where they eat their food.
- who chooses the food they eat.
- what they drink.
- who chooses their drinks.

Use the flip chart as a prompt and try to verbalise what you have heard from them.

Check with them that your re-cap is correct and that you haven't missed anything.

After the group:

Write up the observations and key points and print out the photos.

Week 3 – Discussion Guide

Topic for week: Exercise / Physical Activity

Equipment Required:

Desk top flip chart
Flip chart pens
Wallpaper lining with hand drawn on x 2
Wallpaper lining with hot air balloon drawn on it
Post-it notes in different colours and sizes
Working agreement
Venn diagram target with overlay sheet divided into 6 segments
Small, round, yellow stickers
Ice breaker statements
4 sets of (7) magazine cuttings of activity
Pens
Felt-tip pens
Spare paper
Glue
Scrap books
Copies of activities from last week

Aims: To gain an understanding of the groups views regarding exercise and physical activity.
To investigate the groups opinions of the positive and negative aspects of exercise/physical activity.
To understand more about the barriers to children being active.

Questioning Route:

Opening: *(Equipment required: working agreement, copies of activities from last week, scrapbooks).*
(10 mins)
Re-cap of working agreement.
Re-cap of what they did last week and what you as a facilitator heard – check they agree. Handout copies of the activities and allow them to stick them into their scrapbooks.
Explain that today we are going to talk about different types of activity.

Ice-breaker: *(Equipment required: venn diagram, stickers, ice breaker statements).*
(5 mins)
Place the venn diagram in the centre of the table. After each statement ask the group to place a sticker in a segment of the venn diagram according to

if they agree, are not sure or disagree. Use the segments of the diagram according to the statement being read out, 1-6. (Explain that there are no right or wrong answers).

1). I walk or cycle to school most of the time.
2). I enjoy doing PE at school.
3). After school I prefer to play on my computer or watch TV than anything else.
4). I am active for more than 1 hour each day.
5). I enjoy taking exercise.
6). I think it is important to be active.

48 hour recall activity: *(Equipment required: A4 paper, pens)*
(10 mins)

Handout the 48 hour recall activity sheets. In the first column ask them to write everything they did which they think of as being activity or exercise. In the second column write how long they did this for. In the third column write who they did it with. In the fourth column write why they did it.

e.g.

What exercise?	How long for?	Who with?	Why did it?

Ask:
How difficult is it to remember what you have done?
What factors influence their choice?
Did they record activity or exercise?

Do they think there is a difference between being active and exercise?
(Write up the 2 words on the flip-chart and ask them the definitions).

Activities Picture Sort: *(Equipment required: 4 sets of (7) magazine cuttings).*
(5 mins)

Work in pairs. Ask them to sort the 7 photographs from the healthiest exercise to the least healthy exercise;
- Listen to how they are making their choices.
- Why is some exercise healthier than others?

How much exercise should they do each day? (Write responses on the flip-chart).
- How do they know this? Who did they hear it from?

- Who do they believe most when they are told things?

Hot Air Balloon Activity: *(Equipment required: Wallpaper lining with hot air balloon drawn on it, post-it notes)*
(10 mins)

Ask them to write on post-it notes;

- What they would like to spend more time doing in their spare time?
- What they would like to try?

Ask them:

- Why would they like to try these things?

Stick them on the main part of the balloon. Talk through them as they put them on.

On post-it notes ask them to write;

- What stops them doing it?
- What stops them trying things?

Put them on the ropes holding the balloon down. Talk through them as they put them on.

Benefits of Exercise Activity: *(Equipment required: wallpaper lining with man drawn on x 2, felt tip pens).*
(10 mins)

Ask the group to write on the man as they get ideas;

- On one man benefits of exercise ……..
- On the other man exercise is bad because……
Try and get them to draw on the man the benefits/negative effects they are describing e.g. good for the heart, lungs, etc.

Ending:
(5 mins)

Re-cap over session;
- activity they felt was healthy/unhealthy.
- amount of activity they do/think they should do.
- what activity they would like to try.
- what stops them being activity or trying new things.
- benefits of exercise

Use the flip chart as a prompt and try to verbalise what you have heard from them.

Check with them that your re-cap is correct and that you haven't missed anything.

Explain that you will write out everything they have done today, e.g. hot air balloon and let them have it next week so they can stick it into their scrap books.

Next week they will have their photos back.

After the group:

Write up activities so each member of the group can have a copy for their scrapbook. Write up observations and key points.

Week 4 – Discussion Guide

Topic for week:

Equipment Required:

Desk top flip chart
Flip chart pens
Working Agreement
Copies of activities from last week
Magazine cuttings of people
Carnegie cuttings (x4)
Photo of obese boy eating crisps
Pens
Felt-tip pens
Graffiti wall – wall paper liner
Spare Paper
A3 paper
Glue
Goodie bags

Aims: To discover how the group perceives healthy/unhealthy people.
To gain an understanding of how they view overweight and obese people.
For them to design a healthy lifestyle programme poster.

Questioning Route:

Opening: *(Equipment required: working agreement, copies of activities).*
(5 mins)

Re-cap of working agreement.
Re-cap of what they did last week and what you as a facilitator heard – check they agree. Handout copies of the activities to stick into scrapbooks.

Ice-breaker: *(Equipment required: magazine cuttings of people).*
(10 mins)

Put all the cutting in the middle of the table. Ask 4 children to pick a photo of a healthy person and 4 to pick a photo of an unhealthy person. Ask them to explain their choice.

Swap over and repeat (don't use same cuttings if possible).

Brainstorm: *(Equipment required: Carnegie cuttings (x4), spare paper, pens).*
(1)

(5 mins) Working in pairs. Ask them to make up a story about what they see in their photos.
e.g. what the person does in their free time, why do they look like they do, what type of things do they eat, what about their friends/family?

- Develop any observations relating specifically to weight.
- How important is the way we look?
- What does it say about us?

Brainstorm: *(Equipment required: photo of obese boy eating crisps).*
(2)
(10 mins) Ask them to describe what they see in the photo.
Develop further observations relating to weight.

- How do you think this happened?
- Does it matter – explore any health problems, what will happen to him in the future, etc
- What should we do – explore healthy eating, physical activity.
- How do his family feel about it?

Poster Activity: *(Equipment required: A3 paper, felt-tip pens).*
(20 mins)

Ask the children to design a poster for a healthy lifestyles programme, such as one we might be able to offer someone like in the photo.
Things to include;

- where it is going to happen
- what day/time
- what sort of things would be offered e.g. healthy eating tips, opportunity to exercise, cookery classes
- how would it be run e.g. like a lesson, like a focus group
- what would it be called
- who would run it
- how would you keep the people on it interested
- how would you make it fun
- How should the child and their family find out any project which might help them? How should they be invited to join?

Allow time at the end to talk through each poster.

During this time facilitator and assistant facilitator to look through each pupils photos with them individually and generate some discussion around what has been recorded.

Ending: Re-cap over session;
(10 mins)

Use the flip chart as a prompt and try to verbalise what you have heard from them.

Check with them that your re-cap is correct and that you haven't missed anything.

Graffiti wall - Ask them to write comments, drawings of what they thought of the focus groups. If they enjoyed them, what they enjoyed the most, etc.

Thank the group and hand out goodie bags

Appendix 9 Establishing facilitators and barriers to change - Representative quotes from focus group participants

Theme	Representative quotations
Low consumption of fruit and vegetables	'I don't really like them … especially veg … maybe have one piece of fruit a day' 'Mum fills up the bowl, but I don't have any … she gives it to my little brother' 'I have veg about 3 times a week … definitely not everyday'
Only half the children reported eating breakfast	'I don't eat in the morning' 'No I don't have breakfast … don't feel hungry in the morning … it's too early on a school day' 'No mum gives me money to buy something on the way to school but I prefer to keep it for my lunch'
When given a choice children consumed high fat and high sugar foods	'Mum and dad want to eat meat and vegetables but I prefer McDonalds and KFC' 'Well when you're out with your mates or something and you just go to McDonalds cos it's cheap and quick. Tastes good too' 'I prefer to watch TV and eat crisps'
Most children ate meals in front of the television	'I eat in the front room … watching TV' 'Front room on the floor … as sometimes my bird pinches my food' 'My brother and I sit in my room and watch TV … we always do it … mum doesn't eat until dad gets in from work so she doesn't mind'
Children knew the key healthy eating messages	'You need to have 5 portions of fruit and veg for vitamins' 'We're supposed to have 8 glasses of water a day … I think' 'Fish has oils … like omega 3 in it … that makes it good … brain food my gran says' 'Brown bread is better than white bread cus they take out the vitamins in the white bread' 'Your health is like your life … so if you eat healthily you will be healthy' 'Pizza, crisps, sausage rolls, chocolate … ain't healthy'

Pupils had a good understanding of the health consequences of unhealthy food	'Yeah I try and eat healthy cus I don't want to put on weight or have spots' 'Eating too much … you'll be unhappy … you're not as fit, unable to run around' 'If you don't do a lot of exercise and eat a lot of fatty foods … it's bad for you … might have a heart attack' 'well if he stopped eating all the junk food, like crisps and stuff like that … he would lose weight … and be happy … I don't think he would be bullied'
Children didn't feel at risk of long-term conditions because of their age	'Well … yeah … they say it might give you a bad heart and stuff … but that's for older people really' 'Cus if you're lazy and fat then you can die quicker … but not until you are older … say 30 or summint' 'Well if you're like that then you'll get disease when you're older … like heart disease … blood clots and clogged arteries yuck'
Pupils understood that sedentary behaviour was unhealthy	'TV … that's unhealthy because you just sit there and watch it … your doing nothing … being lazy' 'He sits down all day … too embarrassed to exercise … so he just gets more unhealthy' 'She is healthy cus she is playing netball and that is exercise … he is unhealthy cus he is just sat down watching'
Boys reported doing more team or competitive sports	'Football … with my mates' 'Kickboxing … down at Hortonwood … I train 3 times a week and do competitions and stuff' 'I like football and rugby and cricket and all those sorts of things really'
Girls were more likely to report walking and exercising alone	'I do about 20 minutes per day … walking um … mainly walking' 'I just walk really … do my paper round each night after school … just walking' 'I prefer to do my exercise videos at home on my own … sometimes my mum does them with me'
Pupils knew the recommended amount of exercise they should take each day	'You're meant to do 1 hour every day' '1 hour, that's what it says at McDonalds' 'Ninja turtle – remember to exercise for at least 1 hour per day'

Appendix 10 Findings influencing the design and organisation of the programme - Representative quotes from focus group participants

Theme	Representative quotations
It should be located outside of school	'In a community centre … somewhere where people know' 'Not in school no way. If you were seen going in then you could get bullied' 'I wouldn't want to come back to school … spend too long here anyway'
Children's parents should be involved	'It should be open to families … yeah that's a good idea … then they can learn together' 'The adults could be in a different room, running different activities … like things they should know to be a parent' 'It depends really … if his parents are fat … they are not going to be that bothered cus he is like them … so they all need to go else it won't work'
Children should have the opportunity to try new activities	'I have put about trying different sports … try something new … then you might find something you like' 'I want to do things, something new … but no-where to do it … older kids just ruin it and things'
Participants should be able to take part in regular exercise sessions	'Get fit and have fun. At the gym. You get to do a variety of different sports and get into shape and try lots of healthy foods' 'Exercise … definitely. That's the best way of getting fit'
Participants should have the chance to try new foods	'You could have Jamie Oliver doing some cooking. Giving them new things to try. They might like it' 'New healthy foods … things they don't know about'
Families should learn how to cook	'Learn how to cook … especially parents … so they don't just get take-outs and stuff' 'Cooking … that would be ace. They could learn to cook what they should be eating'
The programme should run after school in the early evening	'Should be in the evening … children have finished school and parents have finished work' 'Time … when children are sat down watching TV after school … just waiting for their tea … give them something to do'

Chance to meet new people and make new friends	'My idea would be … Healthy Plan … every Monday from 5 to 6.30. Have fun and make friends. Feel great about yourself' 'Meet at the community centre and all people the same size. They can discuss about their problems, about why they comfort eat cus that's a big problem … they will meet new people and not be taken the mick out of'
Chance to taste healthy foods	'Health 4 sports … eat and learn about healthy foods … get to taste foods' 'Introduce them to healthy foods … pasta, fruit and veg'
It must be fun	'I would want it to be fun … have a bit of a laugh' 'Fun yeah … make them smile and want to come back'
Staff should not be judgmental	'The staff well… people who don't judge … and are kind and caring'

Appendix 11 Interview Consent Form

Health Promotion
Telford and Wrekin PCT
67 High Street
Madeley
Telford
TF7 5AU
01952 686310

Interview Consent Form

Y W8? Family-Based Weight Management Project

Name of Researcher: Helen Pittson

Please initial box

1. I give my permission for the Y W8? interview to be tape recorded. I understand that the recording will be transcribed and all names will be changed. ☐

2. I agree that quotes may be taken from the interview and used in the writing of reports for the project. ☐

3. I understand that the tape recordings will be kept securely and destroyed after 5 years. ☐

_____	_____	_____
Name of Parent	Date	Signature
_____	_____	_____
Researcher	Date	Signature

Appendix 12 Interview schedule for parents

Interview schedule for semi-structured interview with parents during development of the childhood weight management programme. Interviews will be carried out at home with 6 parents of overweight or obese children who have come forward through the School Nursing Service. The interview consent form will be completed and the interviews will be tape recorded.

The topics to be covered with the stem question are below.

Healthy behaviour:

STEM 1 – Describe a healthy lifestyle for a child
- Eating behaviour
- Exercise

STEM 2 - How does your child's lifestyle compare to this?

Eating habits:

STEM 3 – Tell me about your child's normal eating behaviour;
- What?
- Where?
- When?
- How much?
- How is it prepared?
- What about at school?

STEM 4 – What about other children in the family – are they the same?

STEM 5 – How about yourself (and your partner)?
- What?
- Where?
- When?
- How much?
- How is it prepared?

STEM 6 – Can you think of any healthy changes to your eating behaviour that would be achievable for your family?

STEM 7 – What might make these changes more difficult to achieve?

Activity levels:

STEM 8 – Tell me about your child's activity levels;
- What?
- Where?
- When?
- How long for?

STEM 9 - What about other children in the family – are they the same?

STEM 10 - How about yourself (and your partner)?
- What?
- Where?
- When?

- How long for?

STEM 11 – How much time does your child spend in sedentary activities (by sedentary I mean watching the TV, playing on the computer, etc)

STEM 12 – Can you think of any healthy changes to your activity levels that would be achievable for your family?

STEM 13 – What might make these changes more difficult to achieve?

Techniques for changing behaviour:

STEM 14 – Have you tried to make changes to your family's eating habits or activity levels?
- What?
- How?
- Was it successful? Why?

Design of the programme:

Stem 15 – We are designing a weight management programme for families. What would be the most important aspects for you?
- Venue
- Timing
- Facilitators
- Content
- Other opportunities

Any other comments?

Thank you

Appendix 13 Establishing facilitators and barriers to change - Representative quotes from semi-structured interviews with parents

Theme	Representative quotations
Children eating too much 'junk' food	'I try and get him to eat healthily but he likes all this junk' 'When she goes to the town centre with her friends she just has McDonalds … says it's what all her friends are having' 'Too much junk I know … but it's cheaper and I know they will eat it … if I make something nice they turn their noses up and I end up putting it in the bin … it's a waste'
Continually snacking on high fat or high sugar foods	'He likes to come home from school and watch a bit of TV and have a packet of crisps … says he's always hungry and can't wait until tea' 'If I offer him a snack he always wants sweets or chocolate … there's an argument if he doesn't get it'
High sugar drinks	'I buy them fizzy pop … I try and limit it though cos of all the sugar … sends his little brother loopy' 'Neither of my children will drink water … they like fruit juice and I let them have that because I thought it was healthy … then someone said the other day about how much sugar there is in it'
Portion sizes too big	'He always asks for more … (laughs) I said to him the other day "you're eating more than your dad" well I suppose he's growing so fast' 'If I don't give her enough then she whines until I give her more ... I don't want her to go hungry'
Won't eat vegetables	'I try at every meal … some things get eaten but they have their favourites don't they?' 'I try and hide them in things … saw it in a magazine … it used to work when they were younger but I think they have got wise to it'
Never has breakfast	'She's always up too late. I stand at the bottom of the stairs shouting her but she comes down at the last minutes and then I have to rush her out the door else she's late for school' 'I know she should … well I should as well …but it's enough trouble to get her out of bed … she just says she isn't hungry … mind you I feel the same'
Unhealthy school dinners	'Well they say the school dinners are improving but I don't think so … not from what they tell me they've had to eat' 'I pack her a lunch … sometimes she eats well … a lot of the time though she just eats the bits she wants and leaves the rest'

Meals were convenience foods	'Well it's difficult you know, I work … and when I get back the kids are always starving … you know … and they like different things … so you know it's just easier to do them something quick and easy' 'I go to ASDA … four of their packet meals for a fiver ... everyone can have what they want'
Not enough time to cook meals from fresh ingredients	'It's always such a rush when we get in from work ... these recipes always take ages' 'They make it look so simple on TV ... I do try but if the kids don't like it then it's wasted'
Other family members are not supportive of changes	'I'm interested as I could do with a bit of help myself (laughs) ... but not (husband's name) ... he eats what he likes and doesn't put on any weight .. makes you mad doesn't it?' 'It's not really fair is it? ... not having chocolate and crisps around the house ... I don't see why my other children should go without'
Family members might sabotage efforts	'I'd try at home but she spends a lot of time with my mum ... after school when I'm at work ... not sure what my mum will think ... I know she likes treating her ... likes to see her happy I suppose' 'It could be difficult for us ... you see ... me and (child's name) dad aren't together anymore and she spends weekends with him. They go out for meals and he likes to treat her ... cos he doesn't see her ... I'm not sure he would like to change that'
Child spends too much time on the computer / watching TV	'He's always on the computer ... playing his games ... it keeps him quiet I suppose (laughs)' 'Well ... I know he watches too much ... really ... but I know where he is and we like to watch some things together'
Should be more PE lessons in school	'More sport at school ... yes that would help ... she takes her kit but she never seems to do much in lessons ... by the time they've got changed I think it's nearly time to put their clothes back on ... that's what she says anyway' 'They don't seem to do much at school ... I know when I was at school we did much more. He's never very keen anyway ... I don't think he likes getting changed, I write him notes sometimes ... so, you know, he doesn't have to join in'

Need more local activities for children that are free or low-cost	'I would like her to do more but everything seems to cost so much ... and if I do it for (child's name) then I have to do it for my other children as well' 'Well they started a new class at the leisure centre. She was quite keen ... must have seen a poster or something about it school. Some of her friends go I think. I will try and send her but it's not easy you know ... next she'll need new trainers ... it never ends'
Don't like letting their child out in the neighbourhood	'I don't really like him playing out. There's lots of people around we don't know ... well you can't be too careful can you?' 'exercise, yes definitely … cus they don't do enough at school and I can't let them out at home, they're a bit little … could be dangerous, you know'
Parents don't exercise regularly due to lack of time	'Well no I don't ... no I don't really ... just don't have the time. Once the children are in bed I just want to relax' 'My husband does ... he cycles to work ... we only have one car you see and I need it for the children ... but, no, I don't ...(laughs)'

Appendix 14 Findings influencing the design and organisation of the programme - Representative quotes from semi-structured interviews with parents

Theme	Representative quotations
Parents need to be involved	'Yes parents should definitely be there ... I would want to be ... she wouldn't be able to make changes on her own' 'It would be good to meet with other families and parents just so you feel … you know … you're not alone … sort of'
Should run after school or in the early evening	'Well obviously it would need to be after work ... most parents work now' 'After school or at the weekends ... trouble is they go to lots of clubs after school ... mind you there's always something on at the weekend (laughs)'
Parents should be able to improve their cooking skills	'I would like to be able to cook better ... just simple things ... things I could do that everyone would enjoy' 'I'd like us to cook together. Something we could do together'
Practical ideas for making changes at home	'Well, things that will work ... that's what I need. I get these magazines and they have ideas ... but you just know they won't work so there's no point trying ... I don't know a family they would work in' 'Well I know it's going to be up to me to make the changes ... so any ideas really ... yeah ... obviously the easier the better'
Improve child's confidence	'I'd like him to improve in confidence ... he seems ... well unhappy at times' 'She never wants to do anything ... you know go out. I suppose she lacks confidence. I was a bit like that as a child so I suppose it's no different ... but ... well ... you know ... if it helped that ... well that would be a help'
Opportunity to make new friends	'I'd like her to get to know some other children ... you know ... have some other friends ... people who understand how she feels' 'He's a cheerful lad ... gets on with most people but he mainly hangs around with his brother. It would be nice if he had a few more friends of his own'
Course should be free	'If it was free ... that would make a big difference for families'

Discussions about topics such as comfort eating and bullying	'I was collecting him from school and a child went past and said "bye fatty" ... I was really upset ... but he just brushed it off and said it was always happening. That was when I realised we needed to tackle this ... it's bullying isn't it?' 'Since me and her dad split I've noticed changes ... empty packets under her bed ... you know crisps and biscuits and things ... you know ... I suppose she's eating because of her feelings. I don't know what to do'

Appendix 15 Matrix of change objectives for children - Reduce total energy intake

Performance Objectives (Children)	Personal Determinants					External Determinants	
	Attitudes	Knowledge	Skills and Self-efficacy	Outcome Expectation	Perceived Social Norms	Cues	Reinforcement
PO.1.1 Decrease consumption of high fat foods	A.1.1a Feel positive about making changes to dietary fat intake A.1.1b Express positive attitude toward choosing low fat foods	K.1.1a Know the problems of eating a high fat diet K.1.1b Be able to distinguish between low and high fat foods	SE.1.1a Explain to others the problems of eating a high fat diet SE.1.1b Demonstrate ability to distinguish low and high fat foods SE.1.1c Express confidence in ability to recognise low and high fat foods	OE.1.1a Expect to feel healthier after dietary changes OE.1.1b Expect decrease in consumption of high fat foods to help with weight management OE.1.1c Choose low-fat food options	N.1.1a Recognise that others in the group are decreasing intake of high fat foods N.1.1b Recognise that others in the group are choosing low fat options N.1.1c Accept that normal weight children consume less high fat foods N.1.1d Family members decrease high fat food consumption	C.1.1a Parents buy low fat alternatives C.1.1b Parents serve less high fat foods C.1.1c Low fat foods are available for snacks C.1.1d Parent and family members choose low fat options	R.1.1a Parent praises child for eating less high fat foods R.1.1b Parent and family members decrease intake of high fat foods R.1.1c Parent praises child for choosing low fat options R.1.1d Parent and family members choose low fat options
PO.1.2 Increase intake of fruit and vegetables to 5 portions a day	A.1.2a Express positive attitude towards eating fruit and vegetables	K.1.2a Understand the benefits of eating fruit and vegetables for	SE.1.2 Express confidence in ability to recognise a portion of fruit	OE.1.2a Expect increasing consumption of fruit and vegetables to	N.1.2a Recognise that others in the group are increasing their	C.1.2a Parent makes fruit and vegetables available	R.1.2a Parent praises child for eating more fruit and vegetables

	A.1.2b Express positive attitude towards choosing fruit and vegetables as snacks	a healthy diet K.1.2b Understand what a portion of fruit or vegetables is K.1.2c Understand that fruit and vegetables are a healthy snack alternative	or vegetables	help with weight management OE.1.2b Choose fruit and vegetables as snacks OE.1.2c Increase consumption of fruit and vegetables to 5 portions a day	intake of fruit and vegetables N.1.2b Recognise that others in the group are choosing fruit and vegetables as snacks N.1.2c Accept that normal weight children eat fruit and vegetables N.1.2d Eating fruit and vegetables is a normal part of family life	C.1.2b Parent and family members increase their intake of fruit and vegetables C.1.2c Parent serves vegetables with meals C.1.2d Parent offers fruit for dessert instead of higher sugar and high fat alternatives C.1.2e Parent and family members choose fruit and vegetables as snacks	R.1.2b Parent and family members increase their intake of fruit and vegetables R.1.2c Parent praises child for knowing what a portion of fruit and vegetables is R.1.2d Parent praises child for choosing fruit and vegetables as snacks R.1.2e Parent and family members choose fruit and vegetables as snacks
PO.1.3 Decrease intake of high sugar foods	A.1.3a Feel positive about decreasing intake of high sugar foods A.1.3b Express positive attitude towards choosing	K.1.3a Know the problems of eating a high sugar diet K.1.3b Be able to distinguish between low and high sugar foods	SE.1.3a Explain to others the problem of eating a high sugar diet SE.1.3b Demonstrate ability to	OE.1.3a Expect to feel healthier after dietary changes OE.1.3b Expect decrease in intake of high sugar foods to help with	N.1.3a Recognise that others in the group are decreasing their intake of high sugar foods N.1.3b	C.1.3a Parent buys low sugar alternatives C.1.3b Parent serves less high sugar foods C.1.3c Healthy	R.1.3a Parent praises child for eating less high sugar foods R.1.3b Parent and family members decrease intake of high

	alternatives to high sugar foods		distinguish between low and high sugar foods SE.1.3c Express confidence in ability to recognise low and high sugar foods	weight management OE.1.3c Choose alternatives to high sugar foods	Recognise that normal weight children eat less high sugar foods N.1.3c Family members decrease high sugar food consumption	snacks are available at home C.1.3d Parent and family members choose alternatives to high sugar foods	sugar foods R.1.3c Parent praises child for distinguishing between low and high sugar foods
PO.1.4 Decrease intake of high sugar drinks	A.1.4a Feel positive about decreasing intake of high sugar drinks A.1.4b Express positive attitude towards choosing healthy drinks	K.1.4a Understand the problems of having a high intake of sugary drinks K.1.4b Know the sugar content of high sugar drinks K.1.4c Know the healthy drinks to have	SE.1.4a Explain to others the problem of having a high intake of sugary drinks SE.1.4b Feel confident in choosing healthy drinks	OE.1.4a Expect to feel healthier after dietary changes OE.1.4b Expect decrease in intake of high sugar drinks to help with weight management OE.1.4c Choose healthy drinks	N.1.4a Recognise that others in the group are decreasing their intake of high sugar drinks N.1.4b Recognise that normal weight children drink less high sugar drinks N.1.4c Family members decrease high sugar drink consumption	C.1.4a Parent buys low sugar alternatives C.1.4b Parent serves water or low sugar drinks C.1.4c Water or healthy drinks are available at home C.1.4d Parent and other family members choose healthy drinks	R.1.4a Parent praises child for drinking less high sugar drinks R.1.4b Parent and family members decrease intake of high sugar drinks R.1.4c Parent praises child for choosing healthy drinks R.1.4d Parent and other family members choose healthy drinks
PO.1.5	A.1.5a Feel	K.1.5a	SE.1.5a	OE.1.5a Expect	N.1.5a	C.1.5a Parents	R.1.5a Parents

Decrease intake of processed foods	positive about the benefits of decreasing intake of processed foods A.1.5b Express positive feelings towards eating natural foods	Understand why processed foods are unhealthy K.1.5b Know the problems of eating a diet high in processed foods K.1.5c Understand the benefits of eating natural foods	Explain to others the problems of eating a diet high in processed foods SE.1.5b Feel confident in choosing more unprocessed foods	to feel healthier after dietary changes OE.1.5b Expect decrease in intake of processed foods to help with weight control OE.1.5c Increase consumption of natural (unprocessed) foods	Recognise that others in the group are decreasing their intake of processed foods N.1.5b Recognise that normal weight children eat less processed foods N.1.5c Family members decrease consumption of processed foods	and family members decrease their intake of processed foods C.1.5b Parent and family members increase their consumption of natural foods C.1.5c Unprocessed foods are served at mealtimes C.1.5d Natural foods are available	praise child for decreasing their intake of processed foods R.1.5b Parent and family members increase their consumption of natural foods
PO.1.6 Have a healthy breakfast everyday	A.1.6 Feel positive about eating a healthy breakfast everyday	K.1.6a Know healthy breakfast food options K.1.6b Understand the importance of eating breakfast K.1.6c Understand the sugar content	SE.1.6a Demonstrate having a healthy breakfast SE.1.6b Explain to others the importance of eating breakfast SE.1.6c	OE.1.6a Expect to feel healthier after dietary changes OE.1.6b Expect eating a healthy breakfast to help with weight management OE.1.6c	N.1.6a Recognise that others in the group are having a healthy breakfast N.1.6b Recognise that normal weight children eat a healthy breakfast	C.1.6a Parent and family members have a healthy breakfast everyday C.1.6b Parent encourages child to have breakfast everyday C.1.6c Parent	R.1.6a Parent praises child for eating a healthy breakfast everyday R.1.6b Parent and family members have a healthy breakfast everyday

		on food labels of breakfast cereals	Demonstrate reading food labels of breakfast cereals SE.1.6d Express confidence in ability to eat a healthy breakfast everyday	Choose to eat a healthy breakfast everyday OE.1.6d Choose low sugar breakfast cereals	everyday N.1.6c Family members eat a healthy breakfast everyday	ensures healthy breakfast options are available everyday	R.1.6c Parent emphasises the importance of eating breakfast
PO.1.7 Increase nutritional knowledge	A.1.7a Feel positive about increasing nutritional knowledge A.1.7b Feel positive about learning recommended portion sizes of food A.1.7c Feel positive about using portion control to regulate food intake	K.1.7a Understand which foods are in each of the food groups K.1.7b Demonstrate ability to list which foods are in each of the food groups K.1.7c Understand why we need each of the food groups K.1.7d Know the number of portions we should eat from each of the	SE.1.7a Increased confidence to manage weight SE.1.7b Explain to others which foods are in each of the food groups SE.1.7c Explain to others why we need each of the food groups SE.1.7d Explain to others the number of portions to eat from the food	OE.1.7a Increase in nutritional knowledge helps with weight management OE.1.7b Be able to relate portion size information to servings of food OE.1.7c Use portion control to regulate food intake OE.1.7d Expect to feel healthier after dietary changes	N.1.7a Recognise that others in the group are increasing their nutritional knowledge N.1.7b Recognise that parent is increasing their nutritional knowledge N.1.7c Recognise that others in the group are learning portion sizes N.1.7d Recognise that	C.1.7a Parent and family members use portion control to regulate food intake C.1.7b Parent serves portion controlled food at mealtimes	R.1.7a Parent praises child for increasing nutritional knowledge R.1.7b Parent praises child for understanding the recommended portion sizes R.1.7c Parent praises child for using portion control to regulate food intake R.1.7d Parent and family members use portion control

		food groups every day K.1.7e Learn recommended portion sizes of foods	groups every day SE.1.7e Show others the recommended portion sizes of foods SE.1.7f Express confidence in ability to relate portion size information to servings of food	OE.1.7e Expect regulation of food intake to help with weight management	others in the group are regulating food intake by using portion control N.1.7e Identify that parent is learning portion sizes N.1.7f Family members use portion control to regulate food intake		to regulate food intake
PO.1.8 Self-monitor dietary intake	A.1.8a Feel positive about learning to self-monitor dietary intake A.1.8b Express positive attitude in self-regulating energy intake in-line with observations from self-monitoring	K.1.8a Understand the importance of monitoring dietary intake K.1.8b Know how to regulate energy intake in-line with observations from self-monitoring	SE.1.8a Explain to others the benefits of self-monitoring SE.1.8b Improve accuracy of recorded information SE.1.8c Improve confidence in ability to self-regulate energy intake to assist in weight maintenance	OE.1.8a Expect learning to self-monitor dietary intake to assist in weight control OE.1.8b Recorded dietary intake information will be more accurate OE.1.8c Self-regulate energy intake in-line with observations from self-	N.1.8 Recognise that others in the group are self-regulating their energy intake based on self-monitoring	C.1.8a Parent assists child in self-monitoring C.1.8b Parent prompts child to record dietary intake C.1.8c Parent prompts child to self-regulate energy intake	R.1.8a Parent praises child for learning to self-monitor dietary intake R.1.8b Parent praises child for improving accuracy of monitoring

				monitoring			
PO.1.9 Try new foods	A.1.9 Have a positive attitude towards trying new foods		SE.1.9 Have increased confidence to try new foods	OE.1.9a Expect to like some of the new foods OE.1.9b Introduce new foods into normal diet	N.1.9a Identify that other children in the group are trying new foods N.1.9b Recognise that family members are trying new foods	C.1.9a Parent offers new foods at home C.1.9b Parent and other family members try new foods	R.1.9a Parent praises child for trying new foods R.1.9b Parent and other family members try new foods

Appendix 16 Matrix of change objectives for children – Increase energy output

Performance Objectives (Children)	Personal Determinants					External Determinants	
	Attitudes	Knowledge	Skills and Self-efficacy	Outcome Expectation	Perceived Social Norms	Cues	Reinforcement
PO.2.1 Increase daily physical activity levels to recommended amounts	A.2.1a Feel positive about increasing daily physical activity levels to recommended amounts A.2.1b Express positive attitude towards being more active	K.2.1a Increase understanding of the benefits of physical activity for weight management K.2.1b Be able to state government targets for physical activity K.2.1c Be able to correctly categorise activities according to level of intensity	SE.2.1a Explain to others the importance of physical activity SE.2.1b Be able to accurately monitor physical activity levels SE.2.1c Have ability to set goals for exercise opportunities SE.2.1d Express confidence in taking part in physical activity	OE.2.1a Increasing daily physical activity levels to recommended amounts will help with weight management OE.2.1b Spend more time playing with friends / family OE.2.1c Choose to be more active OE.2.1d Achieve physical activity goals	N.2.1a Recognise that others in the group are increasing their daily physical activity levels to recommended amounts N.2.1b Believe that normal weight children engage in the recommended amount of physical activity everyday N.2.1c Recognise that family members are completing recommended levels of daily physical activity	C.2.1a Parent and family members increase their daily physical activity levels to recommended amounts C.2.1b Parent encourages child to take part in physical activity C.2.1c Parent provides equipment and / or transportation to take part in physical activity	R.2.1a Parent praises child for increasing daily physical activity levels to recommended amounts R.2.1b Parent and family members increase their daily physical activity levels to recommended amounts R.2.1c Parent provides opportunity for daily physical activity
PO.2.2 Try new activities	A.2.2 Have positive attitude towards trying new activities	K.2.2 Know what new activities to try and where to try them	SE.2.2 Express increased confidence to try new activities	OE.2.2a Expect increase in confidence to try new activities	N.2.2a Recognise that other children in the group are trying new	C.2.2a Parent and family members encourage child to try new	R.2.2a Parent and family members try new activities themselves

				OE.2.2b Introduce new activities into normal lifestyle	activities N.2.2b Feel that family encourage them to try new activities N.2.2c Parent and family members try new activities	activities C.2.2b Parent assists child in finding new activities to try C.2.2c Parent provides equipment and / or transportation for child to take part in new activities	R.2.2b Parent praises child for trying new activities R.2.2c Parent and family members encourage child to try new activities
PO.2.3 Limit time spent in sedentary activities	A.2.3 Express positive attitude towards limiting time spent in sedentary activities	K.2.3a Understand the importance of limiting time spent in sedentary activities K.2.3b Monitor time spent in sedentary activities K.2.3c List other non-sedentary activities they enjoy	SE.2.3a Explain to others the importance of limiting time spent in sedentary activities SE.2.3b Feel confident to negotiate peer pressure to engage in sedentary activities	OE.2.3a Expect limiting time spent in sedentary activities to help with weight management OE.2.3b Choose to spend less time in sedentary activities OE.2.3c Spend more time being active with family and friends	N.2.3a Recognise that others in the group are limiting time spent in sedentary activities N.2.3b Feel their normal family lifestyle encourages them to be more active and limit time spent in sedentary activities	C.2.3a Parent and family members assist child in limiting time spent in sedentary activities C.2.3b Parent and family members encourage child to limit time spent in sedentary activities C.2.3c Parent ensures other non-sedentary activities are available for the child	R.2.3a Parent praises child for limiting time spent in sedentary activities R.2.3b Parent and family members limit the time they spend in sedentary activities

Appendix 17 Matrix of change objectives for parents – Reduce total energy intake

Performance Objectives (Parent)	Personal Determinants				
	Attitudes	Knowledge	Skills and Self-efficacy	Outcome Expectation	Perceived Social Norms
PO.3.1 Decrease availability of high fat foods in the home	A.3.1a Feel positive about decreasing amount of high fat foods available in the home A.3.1b Express positive attitude toward offering low fat foods	K.3.1a Know the problems of eating a high fat diet K.3.1b Be able to distinguish between low and high fat foods K.3.1c Parent aware of the impact of their own behaviour on child	SE.3.1a Explain to others the problems of eating a high fat diet SE.3.1b Demonstrate ability to distinguish low and high fat foods SE.3.1c Express confidence in ability to recognise low and high fat foods SE.3.1d Express confidence in assisting child to reduce consumption of high fat foods	OE.3.1a Expect child's decrease in consumption of high fat foods to help with their weight management OE.3.1b Refrain from buying high fat foods OE.3.1c Choose low fat food options to have at home OE.3.1d Put high fat foods out of sight and reach of child OE.3.1e Refrain from serving high fat foods at mealtimes OE.3.1f Reduce own intake of high fat foods OE.3.1g Make low fat options available for snacks OE.3.1h Praise child	N.3.1a Recognise that other parents are decreasing the availability of high fat foods in the home N.3.1b Family members decrease high fat food consumption

				for decreasing intake of high fat foods	
PO.3.2 Increase availability of fruit and vegetables in the home	A.3.2a Feel positive about increasing availability of fruit and vegetables in the home A.3.2b Express positive attitude towards eating fruit and vegetables A.3.2c Feel positive about increasing child's consumption of fruit and vegetables to recommended amounts	K.3.2a Understand the benefits of eating fruit and vegetables for a healthy diet K.3.2b Know the recommended amount of fruit and vegetables to be eaten everyday K.3.2c Understand what a portion of fruit or vegetables is K.3.2d Understand that fruit and vegetables are a healthy snack alternative K.3.2e Parent aware of the importance of role modelling the behaviour they wish to see in their child	SE.3.2a Express confidence in ability to recognise a portion of fruit or vegetables SE.3.2b Be able to explain to others the benefits of eating fruit and vegetables SE.3.2c Express confidence in ability to increase child's consumption of fruit and vegetables to recommended amounts	OE.3.2a Increase child's intake of fruit and vegetables to 5 a day OE.3.2b Expect child's increasing consumption of fruit and vegetables to help with their weight management OE.3.2c Offer child fruit and vegetables as snacks OE.3.2d Purchase a variety of fruit and vegetables when shopping OE.3.2e Have a fruit bowl on display at home within reach of child OE.3.2f Have vegetables cut up for snacks in the fridge at child's eye level OE.3.2g Serve fruit and/or vegetables at every mealtime	N.3.2a Family members choose fruit and vegetables as snacks N.3.2b Recognise that other parents are increasing their child's intake of fruit and vegetables N.3.2c Eating fruit and vegetables is a normal part of family life

				OE.3.2h Parent increases own intake of fruit and vegetables OE.3.2i Praise child for choosing fruit and vegetables as snacks	
PO.3.3 Decrease availability of high sugar foods in the home	A.3.3a Feel positive about decreasing amount of high sugar foods available in the home A.3.3b Express positive attitude toward offering alternatives to high sugar foods	K.3.3a Know the problems of eating a high sugar diet K.3.3b Be able to distinguish between low and high sugar foods K.3.3c Parent aware of the impact of their own behaviour on child	SE.3.3a Explain to others the problem of eating a high sugar diet SE.3.3b Demonstrate ability to distinguish between low and high sugar foods SE.3.3c Express confidence in ability to recognise low and high sugar foods SE.3.3d Express confidence in helping child to decrease intake of high sugar foods	OE.3.3a Expect child's decrease in intake of high sugar foods to help with their weight management OE.3.3b Refrain from buying high sugar foods when shopping OE.3.3c Choose reduced sugar/low sugar food options to have at home OE.3.3d Put high sugar foods out of sight and reach of child OE.3.3e Refrain from serving high sugar foods at mealtimes OE.3.3f Parent reduces consumption of high sugar foods	N.3.3a Recognise that others parents are decreasing the availability of high sugar foods in the home N.3.3b Family members decrease high sugar food consumption

				OE.3.3g Make healthy snacks available at home OE.3.3h Praise child for decreasing intake of high sugar foods	
PO.3.4 Decrease availability of high sugar drinks in the home	A.3.4a Feel positive about decreasing availability of high sugar drinks in the home A.3.4b Express positive attitude toward offering alternatives to high sugar drinks	K.3.4a Understand the problems of having a high intake of sugary drinks K.3.4b Know the sugar content of high sugar drinks K.3.4c Know the healthy drinks to have K.3.4d Parent aware of the impact of their own behaviour on child	SE.3.4a Explain to others the problem of having a high intake of sugary drinks SE.3.4b Feel confident in offering healthy drinks	OE.3.4a Expect child decreasing intake of high sugar drinks to help with their weight management OE.3.4b Refrain from buying high sugar drinks when shopping OE.3.4c Put high sugar drinks out of sight and reach of child OE.3.4d Offer child water or semi-skimmed milk whenever possible OE.3.4e Parent reduces own intake of high sugar drinks OE.3.4f Make healthy drinks available to child	N.3.4a Recognise that others parents in the group are helping their child to decrease their intake of high sugar drinks N.3.4b Family members choose healthy drinks

				OE.3.4g Praise child for choosing healthy drinks	
PO.3.5 Decrease child's intake of processed foods	A.3.5a Feel positive about the benefits of decreasing child's intake of processed foods A.3.5b Express positive feelings towards child eating natural foods	K.3.5a Understand why processed foods are unhealthy K.3.5b Know the problems of eating a diet high in processed foods K.3.5c Understand the benefits of eating natural foods K.3.5d Know how to prepare natural foods for meals K.3.5e Parent aware of the impact of their own behaviour on child	SE.3.5a Explain to others the problems of eating a diet high in processed foods SE.3.5b Feel confident in offering child more unprocessed foods SE.3.5c Feel confident in preparing natural foods for meals SE.3.5d Increase cooking skills	OE.3.5a Expect child decreasing intake of processed foods to help with their weight control OE.3.5b Increase child's consumption of natural (unprocessed) foods OE.3.5c Increase use of natural ingredients when cooking OE.3.5d Refrain from buying processed foods when shopping OE.3.5e Serve unprocessed foods OE.3.5f Parent reduces intake of processed foods	N.3.5a Recognise that other parents are decreasing their child's intake of processed foods N.3.5b Family members decrease consumption of processed foods
PO.3.6 Encourage child to have a healthy breakfast	A.3.6 Feel positive about encouraging child to eat a healthy breakfast everyday	K.3.6a Understand the importance of eating breakfast K.3.6b Know healthy breakfast food options	SE.3.6a Explain to others the importance of eating breakfast SE.3.6b Demonstrate reading food labels of	OE.3.6a Expect encouraging child to eat a healthy breakfast everyday to help with their weight management OE.3.6b Child eats a	N.3.6a Recognise that other parents are encouraging their child to have a healthy breakfast N.3.6b Family members eat a

		K.3.6c Understand the sugar content on food labels of breakfast cereals K.3.6d Parent aware of the importance of role modelling good behaviour	breakfast cereals SE.3.6c Express confidence in ability to encourage child to eat a healthy breakfast everyday	healthy breakfast everyday OE.3.6c When shopping buy healthy breakfast options only OE.3.6d Choose low sugar breakfast cereals OE.3.6e Parent has a healthy breakfast everyday OE.3.6f Praise child for eating a healthy breakfast	healthy breakfast everyday
PO.3.7 Increase nutritional knowledge	A.3.7 Feel positive about increasing nutritional knowledge	K.3.7a Understand which foods are in each of the food groups K.3.7b Demonstrate ability to list which foods are in each of the food groups K.3.7c Understand why we need each of the food groups K.3.7d Know the number of portions we should eat from each of the food	SE.3.7a Explain to others which foods are in each of the food groups SE.3.7b Explain to others why we need each of the food groups SE.3.7c Explain to others the number of portions to eat from the food groups every day SE.3.7d Feel confident in using	OE.3.7a Serve child daily meals according to the Balance of Good Health OE.3.7b Expect increase in nutritional knowledge to help with child's weight management OE.3.7c Use increased nutritional knowledge to decrease child's energy intake	N.3.7 Recognise other parents are increasing nutritional knowledge

		groups every day	nutritional knowledge to help child with weight management		
PO.3.8 Plan and structure mealtimes	A.3.8a Feel positive about planning meals in advance A.3.8b Express positive attitude towards creating structure to mealtimes at home	K.3.8a Understand how to plan healthy, balanced meals K.3.8b Know the benefits of having structured mealtimes	SE.3.8a Demonstrate ability to plan the menu for meals in advance SE.3.8b Have confidence to prepare a shopping list according to the meal plans SE.3.8c Express confidence in getting child to eat meals sat at a dining table	OE.3.8a Have meals at set times during the day OE.3.8b Plan the menu for meals in advance OE.3.8c Prepare a shopping list according to the meal plans OE.3.8d Tell child when meals will be served OE.3.8e Sit down together at a dining table to eat	N.3.8a Recognise that other parents are planning their meals in advance N.3.8b Recognise that other parents are structuring mealtimes N.3.8c Family members sit down at a dining table together to eat meals N.3.8d Believe that other families sit down at a dining table to eat meals
PO.3.9 Serve child controlled portions	A.3.9a Express positive attitude in serving child controlled portion sizes A.3.9b Feel positive about learning recommended portion sizes of food A.3.9c Feel positive about using portion control to regulate	K.3.9a Understand the recommended portion sizes of foods K.3.9b Understand portion sizes of food for child	SE.3.9a Be able to demonstrate the recommended portion sizes of foods SE.3.9b Feel confident to serve child portion controlled meals	OE.3.9a Be able to relate portion size information to servings of food OE.3.9b Use portion control to regulate child's food intake OE.3.9c Expect serving controlled portions to child to help with weight management	N.3.9a Recognise that other parents are learning portion sizes. N.3.9b Recognise that other parents are serving their child controlled portions to regulate energy intake N.3.9c Family members use

	energy intake			OE.3.9d Parent regulates own energy intake by controlling their own portion sizes	portion control to regulate food intake
PO.3.10 Monitor child's energy intake	A.3.10a Feel positive about learning to monitor child's energy intake A.3.10b Express positive attitude towards regulating child's energy intake in-line with observations from monitoring	K.3.10a Understand the importance of learning to monitor child's diet K.3.10b Know how to regulate child's energy intake in-line with observations from monitoring	SE.3.10a Assist child in recording dietary intake information SE.3.10b Explain to others the benefits of monitoring SE.3.10c Help child improve accuracy of recorded information SE.3.10d Improve confidence in ability to regulate child's energy intake to assist in weight maintenance	OE.3.10a Help child regulate energy intake in-line with monitoring information OE.3.10b Expect learning to monitor child's dietary intake to assist in their weight control OE.3.10c Recorded dietary intake information will be more accurate OE.3.10d Self-regulate energy intake in-line with observations from self-monitoring	N.3.10 Recognise that other parents are regulating their child's energy intake based on monitoring
PO.3.11 Read food labels	A.3.11 Have a positive attitude towards reading food labels	K.3.11a Increase understanding and knowledge of food labels K.3.11b Understand basic information regarding fat content of food labels	SE.3.11a Improve confidence in ability to read food labels SE.3.11b Have increased confidence to choose healthier products	OE.3.11a Buy healthier products OE.3.11b Use knowledge to change family dietary habits	N.3.11 Recognise that other parents are increasing their understanding of food labels

		K.3.11c Understand basic information regarding sugar content of food labels K.3.11d Understand basic information regarding salt content of food labels			
PO.3.12 Try new foods	A.3.12a Have a positive attitude towards trying new foods A.3.12b Feel positive about preparing new foods for meals	K.3.12a Learn basic tips about food preparation K.3.12b Parent aware of the impact of their own behaviour on child	SE.3.12a Have increased confidence to try new foods SE.3.12b Express confidence to prepare new foods SE.3.12c Feel confident to offer child new foods	OE.3.12a Expect to like some of the new foods OE.3.12b Serve new foods at home during meals OE.3.12c Offer new foods at home	

Appendix 18 Matrix of change objectives for parents – Increase energy output

Performance Objectives (Parent)	Personal Determinants				
	Attitudes	Knowledge	Skills and Self-efficacy	Outcome Expectation	Perceived Social Norms
PO.4.1 Increase child's daily physical activity levels to recommended amounts	A.4.1a Parent believes they should take some responsibility for physical activity levels of their child A.4.1b Express positive attitude in assisting child to increase their physical activity levels	K.4.1a Parent understands the importance and benefits of physical activity K.4.1b Parent can state government targets for physical activity levels for children and adults K.4.1c Parent can correctly categorise activities according to level of intensity K.4.1d Parents able to list a range of local opportunities for exercise K.4.1e Parents have accurate perception of cost of activities K.4.1f Parent aware of the impact of their own behaviour on child	SE.4.1a Parent expresses confidence in encouraging child to increase physical activity levels SE.4.1b Explain to others the importance of physical activity SE.4.1c Be able to monitor child's physical activity levels SE.4.1d Have confidence to set child physical activity goals	OE.4.1a Parent assists child in increasing daily physical activity levels to recommended amount OE.4.1b Parent spends more time playing with child OE.4.1c Parent assists child in trying new activities (equipment / transportation / money, etc) OE.4.1d Parent encourages child to play with family/friends OE.4.1e Parent increases own physical activity levels OE.4.1f Parent increases availability	N.4.1a Recognise that other parents are assisting their child in increasing their activity levels N.4.1b Believe that other parents are increasing their activity levels N.4.1c Perceive that other families achieve the recommended levels of physical activity

		K.4.1g Parent understands importance of monitoring child's activity levels		of equipment and clothing for physical activity OE.4.1g Increasing child's physical activity levels will assist in their weight management OE.4.1h Help child to regulate physical activity levels in line with monitoring information OE.4.1i Parent praises child for increasing physical activity levels	
PO.4.2 Assist child in limiting time spent in sedentary activities	A.4.2a Parent believes they should take some responsibility for physical activity levels of their child A.4.2b Express positive attitude in assisting child in limiting time spent in sedentary activities	K.4.2a Parent aware of time child spends in sedentary activities K.4.2b Parent aware of strategies to reduce child's sedentary activity time K.4.2c Parent aware of the impact of their own behaviour on child K.4.2d Parent	SE.4.2a Parent expresses confidence in using strategies to negotiate time child spends in sedentary activities at home SE.4.2b Parent able to list a range of other activities child could take part in SE.4.2c Be able to monitor child's sedentary activity levels	OE.4.2a Expect limiting child's sedentary activity time to assist in their weight management OE.4.2b Parent helps child to limit sedentary activity levels in line with monitoring information OE.4.2c Parent limits own sedentary activity time	N.4.2a Recognise that other parents are assisting their child in limit their time spent in sedentary activities N.4.2b Believe that other parents are limiting their own sedentary behaviour N.4.2c Perceive that other families limit their sedentary activity time

		understands importance of monitoring child's sedentary activity levels	SE.4.2d Parent feels they can influence levels of sedentary behaviour of their child by example	OE.4.2d Parent praises child for limiting sedentary activity time	

Appendix 19 Matrix of change objectives and practical strategies for children

Change Objectives	Method	Theoretical Base	Strategy
SE.1.1b, SE.1.1c, K.1.2b, SE.1.2, K.1.3b, SE.1.3b, SE.1.3c, SE.1.4b, SE.1.5b, SE.1.6a, SE.1.6c, SE.1.6d, K.1.7b, SE.1.7b, SE.1.7c, SE.1.7d, SE.1.7e, SE.1.7f, SE.1.8b, SE.1.8c, SE.1.9, SE.2.1a, SE.2.1d, SE.2.2, SE.2.3b	Skill training	Increasing self-efficacy - Social cognitive theory (Bandura, 1982).	Workshop activities. Food and activity diaries. Physical activity sessions.
N.1.1a, N.1.1b, N.1.1d, R.1.1b, R.1.1d, N.1.2a, N.1.2b, C.1.2b, R.1.2b, C.1.2e, R.1.2e, N.1.3a, N.1.3c, C.1.3d, R.1.3b, N.1.4a, N.1.4c, C.1.4d, R.1.4b, R.1.4d, N.1.5a, N.1.5c, C.1.5a, C.1.5b, R.1.5b, N.1.6a, N.1.6c, C.1.6a, R.1.6b, N.1.7a, N.1.7b, N.1.7c, N.1.7d, C.1.7a, R.1.7d, N.1.7e, N.1.7f, N.1.8, N.1.9a, N.1.9b, C.1.9b, R.1.9b, N.2.1a, N.2.1c, C.2.1a, R.2.1b, N.2.2a, N.2.2c, R.2.2a, N.2.3a, R.2.3b	Role modeling	Increasing self-efficacy – SLT (Bandura, 1997).	Workshop discussions and activities. Parent only workshops.
SE.2.1a, SE.2.1c, OE.2.1d	Goal setting	Goal setting / Implementation intentions (Sheeran et al., 2005)	Workshop discussions and activities. Physical activity sessions.
OE.1.7c, OE.1.8a, OE.1.8b, OE.1.8c, SE.2.1b, K.2.3b	Self-monitoring		Workshops discussions and activities. Food and activity diaries.
A.1.1a, A.1.1b, A.1.2a, A.1.2b, A.1.3a, A.1.3b, A.1.4a, A.1.4b, A.1.5a, A.1.5b, A.1.6, R.1.6c, A.1.7a, A.1.7b, A.1.7c, A.1.8a, A.1.8b, A.1.9, A.2.1a, A.2.1b, A.2.2, A.2.3	Persuasive communication	Attitude change – Elaboration likelihood model, Persuasion communication matrix, Social cognitive theory	Workshop discussions and activities. Physical activity sessions.
OE.1.1a, C.1.1a, OE.1.1b, C.1.1b, N.1.1c, OE.1.1c, C.1.1c, OE.1.2a, C.1.2a, OE.1.2b, N.1.2c, OE.1.2c, C.1.2c, N.1.2d, C.1.2d, C.1.2e, OE.1.3a, C.1.3a, N.1.3b, OE.1.3b, C.1.3b, OE.1.3c, C.1.3c, C.1.3d, OE.1.4a,	Cues to action	Goal-related theories Health Belief model (Becker, 1974)	Workshop discussions and activities. Physical activity sessions.

C.1.4a, N.1.4b, OE.1.4b, C.1.4b, OE.1.4c, C.1.4c, C.1.4d, OE.1.5a, C.1.5a, N.1.5b, OE.1.5b, C.1.5b, OE.1.5c, C.1.5c, C.1.5d, OE.1.6a, C.1.6a, N.1.6b, OE.1.6b, C.1.6b, OE.1.6c, C.1.6c, OE.1.6d, SE.1.7a, OE.1.7a, C.1.7a, C.1.7b, OE.1.7d, OE.1.7e, C.1.8a, C.1.8b, C.1.8c, OE.1.9a, C.1.9a, OE.1.9b, C.1.9b, OE.2.1a, C.2.1a, N.2.1b, OE.2.1b, C.2.1b, OE.2.1c, C.2.1c, OE.2.2a, C.2.2a, C.2.2b, N.2.2b, C.2.2c, N.2.3b, OE.2.3a, C.2.3a, OE.2.3b, C.2.3b, C.2.3c, K.2.3c			
C.1.1d, R.1.1a, R.1.1c, R.1.1d, C.1.2b, R.1.2a, R.1.2b, R.1.2c, R.1.2d, R.1.2e, R.1.3a, R.1.3b, R.1.3c, R.1.4a, R.1.4b, R.1.4c, R.1.4d, R.1.5a, R.1.5b, R.1.6a, R.1.6b, R.1.6c, R.1.7a, R.1.7b, R.1.7c, R.1.7d, R.1.8a, R.1.8b, R.1.9a, R.1.9b, R.2.1a, R.2.1b, R.2.1c, R.2.2a, R.2.2b, R.2.2c, OE.2.3c, R.2.3a, R.2.3b	Feedback and reinforcement	Increasing self-efficacy - Social cognitive theory (Bandura, 1982)	Parent only workshops.
K.1.1a, K.1.1b, K.1.2a, K.1.2b, K.1.2c, K.1.3b, SE.1.3b, K.1.4b, K.1.4c, K.1.6c, SE.1.6c, K.1.7b, K.1.7e, OE.1.7b, K.1.8b, K.2.1a, K.2.1c, SE.2.1b, SE.2.3b	Active learning	Increase knowledge - Persuasion communication matrix, Elaboration likelihood model, Social cognitive theory	Workshop discussions and activities. Physical activity sessions.
K.1.1a, K.1.1b, SE.1.1a, K.1.3a, SE.1.3a, K.1.4a, SE.1.4a, K.1.5a, K.1.5b, K.1.5c, SE.1.5a, K.1.6a, K.1.6b, SE.1.6b, K.1.7a, K.1.7c, K.1.7d, SE.1.7b, SE.1.7c, SE.1.7d, SE.1.7e, K.1.8a, SE.1.8a, K.2.1b, SE.2.1a, K.2.2, K.2.3a, SE.2.3a	Awareness raising	Transtheoretical model (TTM)(Prochaska and Declemente, 1983)	Workshop discussions and activities. Physical activity sessions.
N.1.1a, N.1.1b, N.1.1c, N.1.2a, N.1.2b, N.1.2c, N.1.3a, N.1.3b, N.1.4a, N.1.4b, N.1.5a, N.1.5b, N.1.6a, N.1.6b, N.1.7a, N.1.7c, N.1.7d, N.1.8, N.1.9a, N.1.9b,	Self reevaluation	Transtheoretical model (TTM)(Prochaska and Declemente, 1983)	Workshop discussions and activities. Physical activity sessions.

N.2.1a, N.2.1b, N.2.1c, N.2.2a, N.2.3a, N.2.3b			
K.1.8b, SE.1.8b, OE.1.8c, SE.2.1b, K.2.3b	Individualization	Transtheoretical model (TTM)(Prochaska and Declemente, 1983)	Workshop discussions and activities.
OE.2.2b	Guided practice	Increasing self-efficacy - Social cognitive theory (Bandura, 1982)	Physical activity sessions.
SE.2.3b	Planning coping responses	Increase self-efficacy - Attribution theory, Relapse prevention theory	Workshop discussions and activities.

Appendix 20 Matrix of change objectives and practical strategies for parents

Change Objectives	Method	Theoretical Base	Strategy
K.3.1b, SE.3.1b, SE.3.1c, SE.3.1d, K.3.2c, SE.3.2a, SE.3.2b, SE.3.2c, K.3.3b, SE.3.3b, SE.3.3c, SE.3.3d, SE.3.4b, K.3.5d, SE.3.5b, SE.3.5c, SE.3.5d, K.3.6c, SE.3.6b, SE.3.6c, SE.3.7a, SE.3.7b, SE.3.7c, SE.3.7d, OE.3.7a, OE.3.7c, SE.3.8a, SE.3.8b, SE.3.8c, OE.3.8b, OE.3.8c, SE.3.9a, SE.3.9b, OE.3.9a, OE.3.9b, K.3.10b, SE.3.10c, SE.3.10d, OE.3.10c, OE.3.10d, SE.3.11a, SE.3.11b, K.3.12a, SE.3.12a, SE.3.12b, SE.3.12c, SE.4.1a, SE.4.1b, SE.4.1c, OE.4.1a, K.4.2b, SE.4.2a	Skill training	Increasing self-efficacy - Social cognitive theory (Bandura, 1982).	Parent and child workshops. Parent only workshops. Cookery course.
K.3.1c, OE.3.1f, N.3.1a, N.3.1b, K.3.2e, N.3.2a, OE.3.2h, N.3.2b, N.3.2c, K.3.3c, N.3.3a, N.3.3b, K.3.4d, K.3.5e, OE.3.5f, N.3.5a, N.3.5b, K.3.6d, OE.3.6e, N.3.6a, N.3.6b, N.3.7, N.3.8a, N.3.8b, N.3.8c, OE.3.9d, N.3.9a, N.3.9b, N.3.9c, N.3.10, N.3.11, K.3.12b, K.4.1f, N.4.1a, OE.4.1e, K.4.2a, K.4.2c, SE.4.2d, OE.4.2c	Modeling	Increasing self-efficacy – SLT (Bandura, 1997).	Parent only workshops.
OE.3.2a, OE.3.6b, SE.4.1d	Goal setting	Goal setting / Implementation intentions (Sheeran et al., 2005)	Parent only workshops.
SE.3.10a, SE.3.10c, OE.3.10a, OE.3.10c, OE.3.10d, SE.4.1c, OE.4.1h, K.4.1g, K.4.2a, K.4.2d, SE.4.2c	Self-monitoring		Parent only workshops.
A.3.1a, A.3.1b, A.3.2a, A.3.2b, A.3.2c, A.3.3a, A.3.3b, A.3.4a, A.3.4b, A.3.5a, A.3.5b, A.3.6, A.3.7, A.3.8a, A.3.8b, A.3.9a, A.3.9b, A.3.9c, A.3.10a, A.3.10b, A.3.11, A.3.12a, A.3.12b, A.4.1a,	Persuasive communication	Attitude change – Elaboration likelihood model, Persuasion communication matrix, Social cognitive theory	Parent and child workshops. Parent only workshops. Cookery course.

A.4.1b, A.4.2a, A.4.2b			
OE.3.1a, OE.3.1b, OE.3.1c, OE.3.1d, OE.3.1e, OE.3.1g, OE.3.2b, OE.3.2c, OE.3.2d, OE.3.2e, OE.3.2f, OE.3.2g, OE.3.3a, OE.3.3b, OE.3.3c, OE.3.3d, OE.3.3e, OE.3.3g, OE.3.4a, OE.3.4b, OE.3.4c, OE.3.4d, OE.3.4f, OE.3.5a, OE.3.5b, OE.3.5c, OE.3.5d, OE.3.5e, OE.3.6a, OE.3.6c, OE.3.6d, OE.3.7b, OE.3.8a, OE.3.8b, OE.3.8c, OE.3.8d, OE.3.8e, OE.3.9b, OE.3.9c, SE.3.10a, OE.3.10a, OE.3.10b, OE.3.10d, OE.3.11a, OE.3.11b, OE.3.12a, OE.3.12b, OE.3.12c, OE.4.1a, OE.4.1b, OE.4.1c, OE.4.1d, OE.4.1f, OE.4.1g, OE.4.2a	Cues to action	Goal-related theories Health Belief model (Becker, 1974)	Parent and child workshops. Parent only workshops. Cookery course.
OE.3.1f, OE.3.1h, N.3.1b, N.3.2a, N.3.2c, OE.3.2h, OE.3.2i, OE.3.3f, OE.3.3h, N.3.3b, OE.3.4e, OE.3.4g, N.3.4b, OE.3.5f, N.3.5b, N.3.6b, OE.3.6e, OE.3.6f, N.3.8c, OE.3.9d, N.3.9c, OE.4.1e, OE.4.1h, OE.4.1i, SE.4.2d, OE.4.2b, OE.4.2c, OE.4.2d	Feedback and reinforcement	Increasing self-efficacy - Social cognitive theory (Bandura, 1982)	Parent only workshops.
K.3.1b, SE.3.1b, K.3.2c, K.3.2d, K.3.3b, SE.3.3b, K.3.4b, K.3.5d, SE.3.5d, K.3.6c, SE.3.6b, K.3.7b, K.3.8a, SE.3.8a, SE.3.8b, SE.3.9a, OE.3.9a, K.3.10b, SE.3.10c, OE.3.10c, K.3.11b, K.3.11c, K.3.11d, K.3.12a, K.4.1c, K.4.1d, K.4.1e, K.4.1g, SE.4.1c, K.4.2b, SE.4.2b, SE.4.2c	Active learning	Increase knowledge - Persuasion communication matrix, Elaboration likelihood model, Social cognitive theory	Parent and child workshops. Parent only workshops. Cookery course.
K.3.1a, SE.3.1a, K.3.2a, K.3.2b, K.3.2d, SE.3.2b, K.3.3a, SE.3.3a, K.3.4a, K.3.4c, SE.3.4a, K.3.5a, K.3.5b, K.3.5c, SE.3.5a, K.3.6a, K.3.6b, SE.3.6a, K.3.7a, K.3.7c, K.3.7d, SE.3.7a, SE.3.7b, SE.3.7c, K.3.8b, K.3.9a,	Awareness raising	Transtheoretical model (TTM)(Prochaska and Declemente, 1983)	Parent and child workshops. Parent only workshops.

K.3.9b, K.3.10a, SE.3.10b, K.3.11a, K.4.1a, K.4.1b, SE.4.1b, K.4.2a, K.4.2d			
N.3.1a, N.3.2b, N.3.3a, N.3.4a, N.3.5a, N.3.6a, N.3.8a, N.3.8b, N.3.8d, N.3.9a, N.3.9b, N.3.10, N.3.11, N.4.1a, N.4.1b, N.4.1c, N.4.2a, N.4.2b, N.4.2c	Self reevaluation	Transtheoretical model (TTM)(Prochaska and Declemente, 1983)	Parent only workshops.
K.3.9b, SE.3.9a, OE.3.9b, K.3.10b, OE.3.10a, K.4.1g, SE.4.1c, OE.4.1h, K.4.2d, SE.4.2c, OE.4.2b	Individualization	Transtheoretical model (TTM)(Prochaska and Declemente, 1983)	Parent only workshops.
K.3.5d, SE.3.5c, SE.3.5d, OE.3.5b, OE.3.5c, OE.3.5e, K.3.8a, SE.3.8a, SE.3.8b, OE.3.8c, SE.3.10a, SE.3.10c, K.3.11a, K.3.12a, SE.3.12b, SE.4.1d, OE.4.1a	Guided practice	Increasing self-efficacy - Social cognitive theory (Bandura, 1982)	Parent only workshops. Cookery course.
SE.3.6c, K.4.2b, SE.4.2a, SE.4.2d	Planning coping responses	Increase self-efficacy - Attribution theory, Relapse prevention theory	Parent only workshops.
OE.3.1c, OE.3.1d, OE.3.1e, OE.3.1g, OE.3.2e, OE.3.2f, OE.3.2g, OE.3.3b, OE.3.3c, OE.3.3d, OE.3.3e, OE.3.3g, OE.3.4c, OE.3.4d, OE.3.4f, OE.3.8e, OE.3.9b, K.3.10b, OE.3.11a, OE.4.1f	Stimulus control	Counter-conditioning Contingency-contracting (TTM) (Prochaska and Declemente, 1983)	

Appendix 21 Research and Development Approval from Telford and Wrekin PCT

Telford and Wrekin NHS
Primary Care Trust
R & D Office
Sommerfeld House
Sommerfeld Road
Trench Lock
Telford
Shropshire TF1 5RY

Direct Telephone Number: 01952 265142

Mrs Helen Pittson
Researcher Childhood Obesity and Physical Activity
Telford and Wrekin Primary Care Trust
67 High Street
Madeley
Telford
Shropshire TF4 7AU

15 September 2006

Dear Helen

Title: **Family-based weight management project**

Thank you for sending me the documentation related to your research project. We have now received and reviewed all necessary paperwork and are happy to give approval for this research to go ahead within Telford and Wrekin PCT. Details of your research will be held on our research and development database and if appropriate, will be submitted to the National Research Register.

Your research is now covered by NHS indemnity as set out in HSG(96)48. You are required to notify the R&D Co-ordinator of any changes to the research protocol or research staff and to report any adverse events.

We are interested and required to monitor the progress of the project and therefore ask that you inform us of the research outcomes. We will also be conducting an annual 10% audit of research projects held on our database and therefore may approach you in the future with regard to this.

The PCT wishes you every success with your research.

Yours sincerely

[redacted]

Dr Anthony Rathbone
Research & Development Lead Manager
Enc: Research Leaflet
cc Trish Hayward, R&D Co-ordinator

Appendix 22 Ethical approval from Coventry University

Memorandum

Coventry University

Faculty of Health & Life Sciences

To Helen Pillson

Cc Orla Dunn

From
Lesley Watts
Research Manager

Extension 5985 **email** l.watts@coventry.ac.uk **Delivery Point** WF124

Our Reference
PG04b/06

Your Reference

Date

Dear Helen,

Coventry University Ethics Committee

I am pleased to inform you that your application to Coventry University Ethics Committee has been successful.

I apologise for the delay which was caused by my confusion between your amendments to the first application and a subsequent second separate application.

I have enclosed the signed form together with the sponsor's signature on your COREC application form for the relevant page.

Best wishes for your study.

Regards,

[redacted]

Lesley Watts
Secretary
Coventry University Ethics Committee
Tel. 024 7679 5945

Appendix 23 Ethical approval from Shropshire NRES

West Midlands Strategic Health Authority

NHS

Shropshire Local Research Ethics Committee
William Farr House
Mytton Oak Road
Shrewsbury
Shropshire
SY3 8XL

Telephone: 01743 261300
Facsimile: 01743 261309

18th August 2006

RECEIVED
23 AUG 2006

Mrs Helen Pittson
Researcher - Childhood Obesity and Physical Activity
Telford and Wrekin PCT
67 High Street
Madeley
Telford TF7 5AU

Dear Mrs Pittson

Full title of study: **Family-based weight management programme for obese young people and their families.**
REC reference number: **06/Q2601/24**

Thank you for your letter of 14th August 2006, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the research site(s) taking part in this study. The favourable opinion does not therefore apply to any site at present. I will write to you again as soon as one Local Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at sites requiring SSA.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Application	1	
Investigator CV		27 February 2006

Protocol Covering Letter	1	
Peer Review		
Questionnaire: Family Eating and Activity Habits Questionnaire		
Participant Information Sheet: Childs Information Sheet	1	
Participant Information Sheet: Parents Information Sheet	1	08 June 2006
Participant Consent Form: Interview Consent Form	1	08 June 2006
Participant Consent Form: Assent Form Children	1	08 June 2006
Participant Consent Form Parents Pack	1	08 June 2006
Flyer Funder Letter D Lanfear	1	02 March 2006
Childs Questionnaire	1	
Parent Questionnaire	1	
Supervisors CV		
Response to Request for Further Information: Assent Form Children Information Sheet for Children Interview Consent Form Parental Consent Form Parents Information Sheet Family Eating and Activity Habits Questionnaire Protocol Parent questionnaire	2 2 2 2 2 2 2 2 2	14 August 2006

Research governance approval

The study should not commence at any NHS site until the local Principal Investigator has obtained final research governance approval from the R&D Department for the relevant NHS care organisation.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

06/Q2601/24 **Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

[redacted]

Mr Bob Rainford
Chair

Email: julie.ramsey@shropshirepct.nhs.uk

Enclosures: Standard approval
Site approval form

Shropshire Local Research Ethics Committee

LIST OF SITES WITH A FAVOURABLE ETHICAL OPINION

For all studies requiring site-specific assessment, this form is issued by the main REC to the Chief Investigator and sponsor with the favourable opinion letter and following subsequent notifications from site assessors. For issue 2 onwards, all sites with a favourable opinion are listed, adding the new sites approved.

REC reference number:	06/Q2601/24	**Issue number:**	1	**Date of issue:**	18 August 2006
Chief Investigator:	Mrs Helen Pitson				
Full **title of study:**	Family-based weight management programme for obese young people and their families.				

This study was given a favourable ethical opinion by Shropshire Local Research Ethics Committee on 17 August 2006. The favourable opinion is extended to each of the sites listed below. The research may commence at each NHS site when management approval from the relevant NHS care organisation has been confirmed.

Principal Investigator	*Post*	*Research site*	*Site assessor*	*Date of favourable opinion for this site*	*Notes* [1]
Mrs Helen Pitson	Researcher - Childhood Obesity and Physical Activity	T&WPCT	*Shropshire*	*17th August 2006*	

Approved by the Chair on behalf of the REC:

[redacted] *(Signature of Chair/Administrator)*
(delete as applicable)

J Ramsey (Name)

(1) *The notes column may be used by the main REC to record the early closure or withdrawal of a site (where notified by the Chief Investigator or sponsor), the suspension of termination of the favourable opinion for an individual site, or any other relevant development. The date should be recorded.*

Y W8? Questionnaire

What I Am Like

Name _____

	Really True For Me	Sort of True For Me				Sort of True For Me	Really True For Me
a	☐	☐	Some kids would rather play outdoors in their spare time	**BUT**	Other kids would rather watch TV.	☐	☐

	Really True For Me	Sort of True For Me				Sort of True For Me	Really True For Me
1	☐	☐	Some kids find it *hard* to make friends	**BUT**	Other kids find it's pretty *easy* to make friends.	☐	☐
2	☐	☐	Some kids do very *well* at all kinds of sports	**BUT**	Other kids *don't* feel that they are very good when it comes to sports.	☐	☐
3	☐	☐	Some kids are *happy* with the way they look	**BUT**	Other kids are *not* happy with the way they look.	☐	☐
4	☐	☐	Some kids are often *unhappy* with themselves	**BUT**	Other kids are pretty *pleased* with themselves.	☐	☐

	Really True For Me	Sort of True For Me				Sort of True For Me	Really True For Me
5	☐	☐	Some kids have *a lot* of friends	**BUT**	Other kids *don't* have very many friends.	☐	☐
6	☐	☐	Some kids wish they could be a lot better at sports	**BUT**	Other kids feel they are good enough at sports.	☐	☐
7	☐	☐	Some kids are *happy* with their height and weight	**BUT**	Other kids wish their height and weight were *different*.	☐	☐
8	☐	☐	Some kids *don't* like the way they are leading their life	**BUT**	Other kids *do* like the way they are leading their life.	☐	☐
9	☐	☐	Some kids would like to have a lot more friends	**BUT**	Other kids have as many friends as they want.	☐	☐
10	☐	☐	Some kids think they could do well at just about any new sports activity they haven't tried before	**BUT**	Other kids are afraid they might *not* do well at sports they haven't ever tried.	☐	☐
11	☐	☐	Some kids wish their body was *different*	**BUT**	Other kids *like* their body the way it is.	☐	☐
12	☐	☐	Some kids are *happy* with themselves as a person	**BUT**	Other kids are often *not* happy with themselves.	☐	☐
13	☐	☐	Some kids are always doing things with *a lot* of kids	**BUT**	Other kids usually do things *by themselves.*	☐	☐

	Really True For Me	Sort of True For Me				Sort of True For Me	Really True For Me
14	☐	☐	Some kids feel that they are *better* than others their age at sports	**BUT**	Other kids *don't* feel they can play as well.	☐	☐
15	☐	☐	Some kids wish their physical appearance (how they look) was *different*	**BUT**	Other kids *like* their physical appearance the way it is.	☐	☐
16	☐	☐	Some kids *like* the kind of person they are	**BUT**	Other kids often wish they were someone else.	☐	☐
17	☐	☐	Some kids wish that more people their age liked them	**BUT**	Other kids feel that most people their age *do* like them.	☐	☐
18	☐	☐	In games and sports some kids usually *watch* instead of play	**BUT**	Other kids usually *play* rather than just watch.	☐	☐
19	☐	☐	Some kids wish something about their face or hair looked *different*	**BUT**	Other kids *like* their face and hair the way they are.	☐	☐
20	☐	☐	Some kids are very *happy* being the way they are	**BUT**	Other kids wish they were *different.*	☐	☐
21	☐	☐	Some kids are *popular* with others their age	**BUT**	Other kids are *not* very popular.	☐	☐

	Really True For Me	Sort of True For Me				Sort of True For Me	Really True For Me
22	☐	☐	Some kids *don't* do well at new outdoor games	**BUT**	Other kids are *good* at new games right away.	☐	☐
23	☐	☐	Some kids think that they are good looking	**BUT**	Other kids think that they are not very good looking	☐	☐
24	☐	☐	Some kids are *not* very happy with the way they do a lot of things	**BUT**	Other kids think the way they do things is *fine*.	☐	☐

Telford and Wrekin NHS
Community Health Services

Y W8?
Physical Activity Survey

Please can you complete this survey. The survey will help us find out the amount and type of physical activity you currently do. It should only take a couple of minutes to complete. Thanks.

Name: _____

To which age category do you belong? (PLEASE CROSS X ONE BOX ONLY).

Under 16 ☐ 16 – 45 years ☐ Over 45 years ☐

Are you: (please tick) Male ☐ Female ☐

Q1. How important is physical activity to you? (PLEASE CROSS X ONE BOX ONLY).

0 = Not important at all 10 = Extremely important

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10

Q2. How many DAYS a week (on average) do you spend doing the following?

If you are under 16:

Total of 60 minutes on physical activity – at a 'moderate' pace (i.e. similar to brisk walking). (PLEASE CROSS X ONE BOX ONLY).

0	1	2	3	4	5	6	7	D/Know
☐	☐	☐	☐	☐	☐	☐	☐	☐

Total of 40 minutes on an activity that makes you sweat or out of breath. (PLEASE CROSS X ONE BOX ONLY).

0	1	2	3	4	5	6	7	D/Know
☐	☐	☐	☐	☐	☐	☐	☐	☐

If you are over 16:

Total of 30 minutes on physical activity – at a 'moderate' pace (i.e. similar to brisk walking). (PLEASE CROSS X ONE BOX ONLY).

0	1	2	3	4	5	6	7	D/Know
☐	☐	☐	☐	☐	☐	☐	☐	☐

Total of 20 minutes on an activity that makes you sweat or out of breath. (PLEASE CROSS X ONE BOX ONLY).

0	1	2	3	4	5	6	7	D/Know
☐	☐	☐	☐	☐	☐	☐	☐	☐

(Please turn to the next page)

DAY:		
TIME	What did you eat or drink?	Where?
How long did you spend watching TV or playing on your computer today?	minutes ☐	
Did you do any physical activity that lasted at least 10 minutes?	Yes ☐ No ☐	
What did you do?	How long for?	

Y W8? – Nutrition Check
Week 1

The eatwell plate

FOOD STANDARDS AGENCY
food.gov.uk

DAY:

TIME	What did you eat or drink?	Where?

How long did you spend watching TV or playing on your computer today? ☐ minutes

Did you do any physical activity that lasted at least 10 minutes? Yes ☐ No ☐

What did you do?	How long for?

DAY:

TIME	What did you eat or drink?	Where?

How long did you spend watching TV ☐ minutes or playing on your computer today?

Did you do any physical activity that lasted at least 10 minutes? Yes ☐ No ☐

What did you do?	How long for?

Healthy Family Behaviours Questionnaire

To help us know if the Y W8? Programme has helped you to make changes it would be helpful if you could answer the attached questionnaire. It shouldn't take very long. All the questions ask about your normal family life. There are no right or wrong answers.

All the questions ask you to say for each statement how much in the last (or typical) week you or your family did this. Tick the box you feel best fits your answer to each statement. Please leave any questions you feel you can't answer or don't wish to answer.

Completion of this questionnaire is entirely voluntary and the information will be used by the health promotion team at NHS Telford and Wrekin only.

Please answer each statement thinking about your normal family life.

	Never	Hardly Ever	Some of the time	Most of the time	Always
1. We eat meals together as a family.	☐	☐	☐	☐	☐
2. My child drinks fizzy pop at home.	☐	☐	☐	☐	☐
3. We have regular set meal times.	☐	☐	☐	☐	☐
4. We eat in front of the TV.	☐	☐	☐	☐	☐
5. My child has chocolate, biscuits or crisps as snacks.	☐	☐	☐	☐	☐
6. My child exercises at least 5 times a week.	☐	☐	☐	☐	☐
7. We sit at a dining table to eat.	☐	☐	☐	☐	☐
8. As a parent I use food to reward good behaviour.	☐	☐	☐	☐	☐
9. I exercise at least 3 times a week.	☐	☐	☐	☐	☐

	Never	Hardly Ever	Some of the time	Most of the time	Always
10. My child eats when he/she is bored.	☐	☐	☐	☐	☐
11. My child can choose when and for how long they watch TV.	☐	☐	☐	☐	☐
12. My child eats breakfast everyday.	☐	☐	☐	☐	☐
13. I eat chocolate, biscuits or crisps as snacks.	☐	☐	☐	☐	☐
14. We drink water and still drinks at home.	☐	☐	☐	☐	☐
15. We eat out at least once a week.	☐	☐	☐	☐	☐
16. My child eats fruit as dessert or as snacks.	☐	☐	☐	☐	☐

	Never	Hardly Ever	Some of the time	Most of the time	Always
17. My child watches more than 2 hours of television during the day.	☐	☐	☐	☐	☐
18. I eat breakfast everyday.	☐	☐	☐	☐	☐
19. I enjoy being active with my child.	☐	☐	☐	☐	☐
20. My child eats when they feel angry or upset.	☐	☐	☐	☐	☐
21. We have vegetables with main meals.	☐	☐	☐	☐	☐
22. My child plays on the computer everyday.	☐	☐	☐	☐	☐
23. My child can help themselves to unhealthy snacks (e.g. crisps, chocolate) at home.	☐	☐	☐	☐	☐

	Never	Hardly Ever	Some of the time	Most of the time	Always
24. I encourage my child to exercise.	☐	☐	☐	☐	☐
25. I set a good example by eating a healthy diet.	☐	☐	☐	☐	☐

Thank you.

Appendix 28 Y W8? mentor session evaluation sheet

Y W8? Mentor – Session Evaluation

Session Number:

Venue:

Date:

Y W8? Mentor:

How did the session go?

_____
_____
_____

Do you need to follow anything up? If so, what and who with?

_____
_____
_____

Did you cover all the content? YES NO

If no, what wasn't covered?

_____
_____
_____

When will this be covered?

_____
_____
_____

Any other comments

_____
_____
_____

Appendix 29 Post- programme - Interview schedule for parents

Interview schedule for semi-structured interview with parents after completion of the Y W8? programme. Interviews will be carried out at home. The interview consent form will be completed and the interviews will be tape recorded.

The topics to be covered with the stem question are below.

Healthy behaviour:

STEM 1 – Can you describe your child's lifestyle now?
- Eating behaviour
- Exercise

STEM 2 - How does this compare to before you attended Y W8?

Eating habits:

STEM 3 – Tell me about your child's normal eating behaviour now;
- What?
- Where?
- When?
- How much?
- How is it prepared?
- What about at school?

STEM 4 – What about other children in the family – are they the same?

STEM 5 – How about yourself (and your partner)?
- What?
- Where?
- When?
- How much?
- How is it prepared?

STEM 6 – What healthy changes have you made for your child / other children / yourself / your family?

STEM 7 – What were the barriers to achieving these changes?

Activity levels:

STEM 8 – Tell me about your child's activity levels now;
- What?
- Where?
- When?
- How long for?

STEM 9 - What about other children in the family – are they the same?

STEM 10 - How about yourself (and your partner)?
- What?
- Where?
- When?
- How long for?

STEM 11 – How much time does your child spend in sedentary activities (by sedentary I mean watching the TV, playing on the computer, etc). how does this compare to pre-Y W8?

STEM 12 – Can you think of any healthy changes to your activity levels that would be achievable for your family?

STEM 13 – What were the barriers to achieving these activity changes

Techniques for changing behaviour:

STEM 14 – What techniques or tools did you use to assist you in changing your child's behaviour? What worked well and what was more difficult?

Design of the programme:

Stem 15 – How could we improve the programme?

- Venue
- Timing
- Facilitators
- Content
- Other opportunities
- Continued support

Any other comments?

Thank you

Y W8? Project Evaluation

(To be completed by child)

1. Since attending Y W8? have you;
   (please tick as many boxes that apply to you)

Made new friends ☐ Increased in confidence ☐

Decreased clothes size ☐ Feel happier ☐

Find school better ☐ Changed body shape ☐

Feel healthier ☐ Feel fitter ☐

2. How would you rate the Y W8? workshops?

Very good ☐ Good ☐ Fair ☐ Poor ☐

3. Were there any workshops that you found really useful or any that were not so useful? *(please list sessions)*

Useful	Not so useful

4. Do you think the workshops were;

Too long ☐ Too short ☐ Just right ☐

5. How would you rate the Y W8? activity sessions?

Very good ☐ Good ☐ Fair ☐ Poor ☐

6. Have these sessions increased your ability and confidence to play sports and join in activities?

Yes ☐ No ☐

7. Has the project given you the confidence to try new activities?

Yes ☐ No ☐

8. How confident are you that attending the Y W8? project will help you to manage your weight in the future? *(1 = not confident, 5 = very confident)*

1 2 3 4 5

9. Do you think the length of the project (12 weeks) was;

Too long ☐ Too short ☐ Just right ☐

10. If you attended, how would you rate the walk up the Wrekin at half-term?

Very good ☐ Good ☐ Fair ☐ Poor ☐

11. What were the best things about Y W8?

12. What were the worst things about Y W8?

13. What other things could have been included to help you more?

14. How would you rate the following?

	Very Good	Good	Fair	Poor
Delivery of workshops	☐	☐	☐	☐
Delivery of activity sessions	☐	☐	☐	☐
Y W8? folder	☐	☐	☐	☐
Y W8? programme in general	☐	☐	☐	☐
Quality of facilities/equipment	☐	☐	☐	☐
Personal satisfaction rating	☐	☐	☐	☐

15. What did you think of the 'freebies'?

	Very Good	Good	Fair	Poor
Y W8? rucksack	☐	☐	☐	☐
Pedometer	☐	☐	☐	☐
Wristband	☐	☐	☐	☐
Waterbottles	☐	☐	☐	☐

16. What changes have you managed to make since attending Y W8?

17. Any other comments?

Thank you

Y W8? Project Evaluation

(To be completed by parent)

1. As a result of the Y W8? project do you feel that your child;
   (please tick as many boxes that apply)

Has made new friends	☐	Is more confident	☐
Has decreased clothes size	☐	Is happier	☐
Is doing better at school	☐	Has changed body shape	☐
Is healthier	☐	Is fitter	☐

2. How would you rate the Y W8? parent and child workshops?

Very good ☐ Good ☐ Fair ☐ Poor ☐

3. How would you rate the Y W8? parent education and support sessions?

Very good ☐ Good ☐ Fair ☐ Poor ☐

4. Were there any elements of these sessions that you found really useful or any that were not so useful? *(please list sessions)*

Useful	Not so useful

5. Were there any topics we didn't cover that you would have liked more information on?

6. How confident do you feel in being able to support your child with their future weight management? *(1 = not confident, 5 = very confident)*

1 2 3 4 5

7. Has the Y W8? project enabled other members of the family to make positive changes to achieve a healthier lifestyle

Yes ☐ No ☐

8. Has your child started participating in any new physical activities as a result of Y W8?

Yes ☐ No ☐

9. If you attended, how would you rate the Feeding the Family Cooking Course?

Very good ☐ Good ☐ Fair ☐ Poor ☐

10. If you attended the cooking course, have you made any changes through attending? (e.g. shopping habits, more use of natural foods, variety).

11. How would you rate the following?

	Very Good	Good	Fair	Poor
Content of information pack	☐	☐	☐	☐
Application arrangements	☐	☐	☐	☐
Professionalism of staff	☐	☐	☐	☐
Delivery of workshops	☐	☐	☐	☐
Y W8? folder	☐	☐	☐	☐
Y W8? 2 Get Cooking folder	☐	☐	☐	☐
Y W8? programme in general	☐	☐	☐	☐
Personal satisfaction rating	☐	☐	☐	☐

12. What changes has your child managed to make since attending Y W8?

13. What changes have you managed to make for yourself or the rest of your family?

14. Any other comments?

Thank you

Appendix 32 Questionnaire for non-starters

YW8?
Shropshire Community Health NHS Trust
Wrekin Housing Trust Building (Ground Floor)
Colliers Way
Old Park
Telford
TF3 4AW

YW8@nhs.net

01952 217480

(DATE)

Dear (enter names),

You and (Name of child) recently enrolled on the YW8? Program and underwent an assessment with (mentor Name).

In order that we can improve our service we would be grateful if you could advise us as to why you decided not to join the programme.

Would you therefore be kind enough to complete the enclosed feedback form return it in the envelope provided?

Yours sincerely,

(Sign name)
Y W8? Team

Please circle the most appropriate answer giving more details in section provided below.

Was the venue going to be difficult for you to get to?

Yes No

Was the time and day inconvenient for you?

Yes No

Did you feel that you did not get enough information at your initial appointment?

Yes No

Whose decision was it not to start the programme?

Parent Child

Is now just the wrong time for you to be considering doing the programme?

Yes No

Would you like us to contact you about rejoining a future programme?

Yes No

Was child care for other children an issue for you?

Yes No

Any other comments

Thank you for taking the time to complete and return this feedback form.

Appendix 33 Questionnaire for non-completers

YW8?
Shropshire Community Health NHS Trust
Wrekin Housing Trust Building (Ground Floor)
Colliers Way
Old Park
Telford
TF3 4AW

YW8@nhs.net

01952 217483

(DATE)

Dear (enter names),

I was sorry to hear that you felt unable to complete the Y W8? Programme. We constantly strive to improve our service and help families to make small, sustainable changes that will have a beneficial effect in the long-term. To enable us to ensure our service meets the needs of families would you kindly complete the enclosed questionnaire and return in the envelope provided.

Alternatively, if you would like to discuss any of the comments / issues please phone me on 01952 217483 and I would be happy to listen to your comments.

Yours sincerely

(Helen Pittson)

Encl

Please circle the most appropriate answer giving additional information in the boxes provided.

Prior to starting Y W8? how important was it for you to start making changes?

Not important Quite important Important Very important

Do you feel, as a parent, you were ready to make changes?

Yes No

Do you feel your child was ready to make changes?

Yes No

Which of the sessions did you find useful?

Is there anything that you feel we could have improved on?

Did you try to make any changes that were as a result of being on the programme?

Whose decision was it to stop the programme?

Parent Child

Any other comments.

Thank you for taking the time to complete and return this form.

Appendix 34 Number of children and parents attending for pre-assessment and recruitment method for each of the 11 cohorts

	Pre-assessment		
	Children	Parents	Recruitment method
Apr 2006	12	12	Self-referral = 6; GP = 2;School nurse = 2; Dietician = 2
Sep 2006	9	8	Self-referral = 2; School nurse = 3; Paediatrician = 3; Adult weight management service = 1
Jan 2007	9	7	Self-referral = 2; GP = 2; School nurse = 3; Paediatrician = 1; Dietician = 1
Apr 2007	15	13	Self-referral = 4; GP = 3; School nurse = 5; Paediatrician = 1; Dietician = 1; Adult weight management service = 1
Sep 2007	13	12	Self-referral = 4; GP = 2; School nurse = 4; Paediatrician = 1; Dietician = 1; Adult weight management service = 1
Jan 2008	11	11	Self-referral = 4; GP = 1; School nurse = 5; Dietician = 1
Apr 2008	11	9	Self-referral = 3; GP = 3; School nurse = 4; Adult weight management service = 1
Sep 2008	12	9	Self-referral = 5; GP = 2; School nurse = 5
Jan 2009	10	10	Self-referral = 4; GP = 2; School nurse = 4
Apr 2009	12	9	Self-referral = 3; GP = 1; School nurse = 4; Paediatrician = 1; Dietician = 1; Adult weight management service = 2
Sep 2009	8	8	Self-referral = 2; GP = 1; School nurse = 4; Adult weight management service = 1
Totals	122	108	

Appendix 35 Gender and ethnicity of children and parents at pre-assessment, non-starters and non-completers for each of the 11 cohorts

	Children						Parents					
	Pre-assessment		Non-starters		Non-completers		Pre-assessment		Non-starters		Non-completers	
	Gender (n)	Ethnicity (n)	Gender (n)	Ethnicity (n)	Gender (n)	Ethnicity (n)	Gender (n)	Ethnicity (n)	Gender (n)	Ethnicity (n)	Gender (n)	Ethnicity (n)
Apr 2006	♀ = 9 ♂ = 3	W = 11 M = 1			♀ = 2	W = 2	♀ = 12	W = 12			♀ = 2	W = 2
Sep 2006	♀ = 7 ♂ = 2	W = 5 A = 2 B = 2			♀ = 1	W = 1	♀ = 6 ♂ = 2	W = 4 A = 2 B = 2			♀ = 1	W = 1
Jan 2007	♀ = 5 ♂ = 4	W = 6 A = 3			♀ = 1	W = 1	♀ = 7	W = 5 A = 2			♀ = 1	W = 1
Apr 2007	♀ = 4 ♂ = 11	W = 14 M = 1	♂ = 2	W = 1 M =1	♂ = 1	W = 1	♀ = 12 ♂ = 1	W = 12 M = 1	♀ = 2	W = 1 M = 1	♀ = 1	W = 1
Sep 2007	♀ = 10 ♂ = 3	W = 11 M = 2			♀ = 2 ♂ = 2	W = 3 M = 1	♀ = 12	W = 11 M = 1			♀ = 4	W = 3 M = 1
Jan 2008	♀ = 5 ♂ = 6	W = 11			♀ = 2 ♂ = 2	W = 4	♀ = 8 ♂ = 3	W = 11			♀ = 3 ♂ = 1	W = 4
Apr 2008	♀ = 8 ♂ = 3	W = 11			♀ = 4 ♂ = 1	W = 5	♀ = 9	W = 9			♀ = 4	W = 4
Sep 2008	♀ = 7 ♂ = 5	W = 11 A = 1	♀ = 1	W = 1	♀ = 4 ♂ = 1	W = 5	♀ = 8 ♂ = 1	W = 8 A = 1	♀ = 1	W = 1	♀ = 4	W = 4
Jan 2009	♀ = 7 ♂ = 3	W = 9 M = 1			♀ = 2	W = 1 M = 1	♀ = 10	W = 10			♀ = 2	W = 2
Apr 2009	♀ = 8 ♂ = 4	W = 12	♀ = 1 ♂ = 1	W = 2	♂ = 1	W = 1	♀ = 9	W = 9	♀ = 2	W = 2	♀ = 1	W = 1
Sep 2009	♀ = 3 ♂ = 5	W = 6 A = 2	♀ = 1 ♂ = 1	W = 2	♀ = 1 ♂ = 1	W = 1 A = 1	♀ = 7 ♂ = 1	W = 6 A = 2	♀ = 1 ♂ = 1	W = 2	♀ = 2	W = 1 A = 1
Totals	122		7		28		108		7		26	

Key for ethnicity: W = white, M = mixed, A = Asian, B = black

Telford and Wrekin NHS
Primary Care Trust

Health Promotion
Telford and Wrekin PCT
67 High Street
Madeley
Telford
TF7 5AU

01952 686310

Information Sheet for Children

The Y W8? Project

Part 1

We are asking if you would agree to take part in the Y W8? (Why Weight?) research project. Before you decide if you want to join in it's important to understand why the research is being done and what it will involve for you. So please read this leaflet carefully. Talk about it with your family, friends, teacher or doctor if you want to.

Thank you for reading this.

Why are we doing this research?

The Y W8? project is about helping you to change unhealthy eating and exercise habits into healthier ones. The project will give you the chance to try new activities, learn about healthy foods and make new friends.

This study will tell us if this project is successful in helping you and your family to make changes to your normal life.

Do I have to take part?

No! It is up to you. If you do, you will be given this information sheet to keep and be asked to sign a form. **You are free to stop taking part at any time during the research without giving a reason**.

What will happen to me if I decide to take part?

One of 2 things may happen. You may be randomly put on the programme, which means you will start on the Y W8? programme immediately, or you may be put on a waiting list and asked to wait until the next Y W8? programme (about 3 months). Whichever group you are in, you will still be involved with the study. If you are on the waiting list we would still like to take your weight and height. We need to do this so we can check that the programme works.

When it is your turn to start the programme you and one of your parents will need to attend the Y W8? project at Telford College of Arts and Technology (TCAT) from 4.30pm – 6.30pm every Friday for 12 weeks.

During the sessions you will have the chance to learn about healthy eating, join in a fun activity session, try new things and make new friends. You may be asked to keep a food diary or wear a step counter during the week between the sessions. This is to help you change to healthier habits.

At the first and last sessions of the project we will need to take your weight and height. We will also ask you to complete a simple questionnaire.

Contact Details

If you would like further information about the study, or have any concerns during the study, please contact;

Helen Pittson Tel: 01952 686312 Mob: 07974 154628

Thank you for reading so far – if you are still interested, please go to Part 2.

Part 2

What happens when the research project stops?

At the end of the project we will give you information about how to continue with the changes you have made. This might be where and when you can go swimming, a particular activity you are interested in or what is going on at your leisure centre.

What if there is a problem?

If you are worried about anything to do with the project then you should speak to your parent. You may decide you want to talk to the researchers who will do their best to answer your questions.

Will anyone else know I'm doing this?

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which is used will have your name and address removed so that you cannot be recognized from it.

Who has reviewed the study?

Before any research goes ahead it has to be checked by an Ethics Committee. They make sure that the research is OK to do. This project has been checked by the Shropshire Research Ethics Committee and Coventry University Ethics Committee.

Thank you for reading this – please ask any questions if you need to.

Health Promotion
Telford and Wrekin PCT
67 High Street
Madeley
Telford
TF7 5AU

01952 686310

Parents Information Sheet

Y W8? Family-Based Weight Management Project

Part 1

You and your child are being invited to take part in the Y W8? (Why Weight?) family-based weight management research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish.

- Part 1 tells you the purpose of this study and what will happen to you if you take part.
- Part 2 gives you more detailed information about the conduct of the study.

Please ask us if there is anything that is not clear or if you would like more information. Thank you for taking time to decide whether or not you and your child wish to take part.

What is the purpose of the research project?

The Y W8? project is about change – specifically about learning to change unhealthy eating and exercise habits into healthier ones. The project will give you the practical advice and support you need to help you and your child make these changes, get more active and control your weight.

The project is a student research project based in Telford and Wrekin Primary Care Trust. This study will tell us if this project is successful in helping you and your child to make lifestyle changes, whether this type of project can be successful in Telford and if the project should be expanded to include more families and children of other ages.

Do we have to take part?

No. It is up to you and your child to decide whether or not to take part. If you do, you will be given this information sheet to keep and be asked to sign a consent form. You are both free to withdraw at any time and without giving a reason.

What will happen to us if we decide to take part?

One of 2 things may happen. You may be randomly put on the programme, which means you will start on the Y W8? programme immediately, or you may be put on a waiting list and asked to wait until the next Y W8? programme (about 3 months). Whichever group you are in, you will still be involved with the study. If you are on the waiting list we would still like to take your child's weight and height. We need to do this so we can check that the programme works.

When it is your turn to start the Y W8? programme you and your child will be asked to attend the Y W8? project at Telford College of Art and Technology (TCAT) from 4.30pm – 6.30pm every Friday for 12 weeks. During the first and last sessions of the project we will need to take your child's weight and height. We will also ask you and your child to complete a questionnaire.

What happens at the end of the Y W8? project?

At the end of the project you will receive information about other healthy lifestyle services run by Telford and Wrekin Primary Care Trust which you and your child can join. We will also give you information about exercise classes and other activities for both children and adults that take place at local leisure centres.

Will my taking part in the study be kept confidential?

Yes. All the information about your participation in this study will be kept confidential. The details are included in Part 2.

Contact Details

If you would like further information about the study, or have any concerns during the study, please contact;

Helen Pittson Tel: 01952 686312 Mob: 07974 154628

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study?

You are free to withdraw at any time. If you do decide to withdraw we will ask for your permission to use data collected up to that point – if you do not want us to have the data then it will be destroyed.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions (01952 686312). If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure (01952 222322).

Will our taking part in this study be kept confidential?

All information which is collected about you and your child during the course of the research will be kept strictly confidential. The procedures for handling, processing, storage and destruction of data are compliant with the Data Protection Act 1998. Participants will not be identified as individuals in any writing up of the study.

What will happen to the results of the research study?

The results of the study will be used in a student research project. It is hoped that these results will be published. You will not be identified in any report or publication unless we have your consent to release such information.

Who is organising and funding the research?

Telford and Wrekin Primary Care Trust are working in partnership with the Health Science Research Centre at Coventry University to organize this research. The study is being funded by Sport England.

Who has reviewed the study?

This study was given a favourable ethical opinion for conduct in the NHS by the Shropshire Research Ethics Committee and Coventry University Ethics Committee.

If you are happy to take part, and are satisfied with the explanations from the research team, you will be asked to sign a consent form. If your child is happy to take part they will be asked to sign an 'assent' form with you, if they want to. You will be given a copy of the information sheet and signed consent/assent forms to keep for your records.

Thank you for taking the time to read this information sheet.

Appendix 38 Child assent form

Health Promotion
Telford and Wrekin PCT
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Telford
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01952 686310

Assent Form For Children

(to be completed by the child and their parent)

Y W8? Family-Based Weight Management Project

Please circle all the statements you agree with:

Have you read (or had read to you) about this project?	Yes / No
Has somebody else explained this project to you?	Yes / No
Do you understand what this project is about?	Yes / No
Have you asked all the questions you want?	Yes / No
Have you had your questions answered in a way you understand?	Yes / No
Do you understand it's OK to stop taking part at any time?	Yes / No
Are you happy to take part?	Yes / No

If any answers are 'no' or you **don't** want to take part, **don't** sign your name!

If you do want to take part, please write your name and today's date

Your name _____

Date _____

Your parent must write their name here too if they are happy for you to do the project.

Print name _____

Sign _____

Date _____

The researcher who explained this project to you needs to sign too:

Print name _____

Sign _____

Date _____

Thank you for your help.

Appendix 39 Parent consent form

Health Promotion
Telford and Wrekin PCT
67 High Street
Madeley
Telford
TF7 5AU

01952 686310

Parental Consent Form

Y W8? Family-Based Weight Management Project

Name of Researcher: Helen Pittson

Please initial box

4. I confirm that I have read and understand the information sheet dated 05/06/07 (version 4.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

5. I understand that my and my child's participation is voluntary and that we are free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

6. I understand that the data collected during the study will be used for a student research project. ☐

7. I agree to myself and my child taking part in the above study. ☐

_____	_____	_____
Name of Parent	Date	Signature
_____		
Name of Child		
_____	_____	_____
Name of Person taking consent (if different from researcher)	Date	Signature
_____	_____	_____
Researcher	Date	Signature

Appendix 40 Presentations, posters, papers and prizes concerning the Y W8? Programme

Presentations

Pittson, H., Dunn, O., and Wallace, L. A Successful Childhood Obesity Treatment Programme: The Y W8? Project. 3rd National Obesity and Health Conference. 19th - 20th March 2007

Pittson, H. Tackling Obesity in Children and Young People – everybody's concern and interest, but what can partners contribute towards this important agenda? "Take Your Partners?" Making the most of our environment and partnerships to increase activity levels in the West Midlands. The 2nd Annual Conference for the Physical Activity Network for the West Midlands. 27th March 2007

Pittson, H., Dunn, O., and Wallace, L. Helping Families with Obese Children Change Their Diet and Exercise Behaviours: The Y W8? Project. 15th UKPHA Annual Public Health Forum 2007. 28th - 29th March 2007

Pittson, H. Telford's local approach to tackling childhood obesity: The Y W8? Project. 10th Annual Achieving Excellence in Public Health Conference West Midlands. 10th May 2007

Pittson, H. NOF 2006 Award Winner: The Y W8? Project. The National Obesity Forum Conference 2007. Monday 15th October – Tuesday 16th October 2007

Pittson, H. Developing services for childhood obesity programmes. 5th National Conference on Obesity and Health. 27th – 28th April 2009

Pittson, H. Developing services for childhood obesity programmes - Seminar. 5th National Conference on Obesity and Health. 27th – 28th April 2009

Pittson, H. Y W8? – Childhood Obesity programme. Child Weight Management Interventions in the West Midlands. 4th February 2010

Pittson, H., and Wallace, L. Helping families with obese children change their diet and exercise behaviour: The Y W8? Programme. Midlands Health Psychology Network Annual Conference. 11th February 2010

Posters

Pittson, H., and Wallace, L. Helping Families with obese children change their diet and exercise behaviours: The Y W8? Programme. HSRN / SDO Network Conference. June 2010 (poster)

Papers

Pittson, H., and Wallace, L. (2010) 'Weight management programme for children'. *Primary Health Care* 20 (5), 16-21

Pittson, H., and Wallace, L. (2011) 'Using intervention mapping to develop a family-based childhood weight management programme'. *Journal of Health Service Research and Policy* 16 (S1), 2-7

Prizes

The Y W8? Project won the National Obesity Forum 2006 Excellence in Weight Management Award for Children and Adolescents.

The Y W8? Project won the National Obesity Forum 2006 overall national winners award for Best Practice in Primary Care.

Helen Pittson won the Heart of England NHS Foundation Trust Prize for Innovation in 2007.

Helen Pittson was awarded a travelling fellowship from the Winston Churchill Memorial Trust in 2007. For her fellowship she spent 6 weeks visiting various childhood obesity treatment centres in the United States.

The Y W8? Team won the Improving Health and Reducing Inequalities Award at the West Midlands Health and Social Care Awards 2009.

The Y W8? Team won the Chair's Team Award at NHS Telford and Wrekin's Celebrating Success 2009

Y W8? was highly commended in the Improvement Foundation's Guy Rotherham Award 2009

The Why Weight? Service won the Team of the Year award at the West Midlands Excellence in Public Health Awards 2012

Appendix 41 Published paper 1

Original research

Using intervention mapping to develop a family-based childhood weight management programme

Helen Pittson, Louise Wallace[1]

Child Nutrition and Obesity, Telford and Wrekin Community Health Services, Telford; [1]Applied Research Centre, Health and Lifestyles Interventions, Coventry University, Coventry, UK

Objectives: To develop, implement and evaluate a family-based childhood weight management programme.

Methods: Programme development utilized Bartholomew's Intervention Mapping framework. This six step structured approach provides planners with a framework that links determinants of health behaviours with performance objectives and strategies to be incorporated into programme design. Using this process a needs analysis and literature review were undertaken, a steering group formed, six focus groups (with a total of n = 47 pupils) were completed and six interviews took place with parents. The determinants were combined with relevant theories to develop the programme. Y W8? is a 12 week course for families with children aged 8–13 years designed to assist with weight management. Participants' height, weight and physical activity levels along with self-esteem scores for children are recorded pre- and post-intervention and at three, six and 12 month follow-up. This paper documents post-course results at 12 weeks.

Results: Preliminary results showed children (mean pre-BMI = 28.48 (±4.44), mean post-BMI = 27.48 (±4.45; P = <0.001) and parents (mean pre-BMI = 30.77 (±6.21), mean post-BMI = 30.41 (±6.17; P = 0.017) decreased their BMI over the 12 weeks. These results compare favourably with similar programmes in the UK.

Conclusions: Intervention mapping was a useful approach for developing a theory based intervention. Results suggest Y W8? improves the body mass index (BMI) of children and parents at 12 weeks. Further work, including a randomized controlled trial (RCT), will confirm this, investigate the longer-term effectiveness and determine how the effects are mediated by psychological processes.

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Appendix 42 Published paper 2

WEIGHT MANAGEMENT PROGRAMME FOR CHILDREN

Helen Pittson and Louise Wallace describe the set-up and outcome of a scheme to help parents and their children to lead healthier lifestyles

Summary

NHS Telford and Wrekin is working with Coventry University to develop, implement and evaluate a local weight management programme for children and their families called 'Y W8?'. The programme, which is underpinned by health psychology research, overcomes complex barriers to losing weight by offering families tailored solutions. It was developed using an intervention mapping method to ensure effective decision making at every step in intervention planning, implementation and evaluation. Results from the 12-month pilot demonstrate success in supporting children and their parents to lose weight and a high level of satisfaction with the programme. Further work is planned to compare the results with a waiting list control group and to follow the families in the longer-term to ascertain whether positive lifestyle changes have been sustained.

Keywords
Childhood obesity, lifestyle, overweight, parents, weight management

Appendix 43 Glossary of terms and abbreviations

ACES	Active Children Eating Smart
ADP	Air displacement plethysmography
ANOVA	Analysis of variance
ARC HLI	Applied Research Centre in Health and Lifestyle Interventions
ATM	Antecedent, target, measurement approach
AWMS	Adult weight management service
BCT	Behaviour change technique
BIA	Bioelectrical impedance analysis
BMA	British Medical Association
BME	Black and minority ethnic
BMI	Body mass index
BP	Blood pressure
CALO-RE	Coventry, Aberdeen and London - Refined
CBIS	Children's body image scale
CCG	Clinical Commissioning Group
CHD	Coronary heart disease
CHEAT	Children's Eating Attitudes Test
CI	Confidence interval
CIPR	Chartered Institute of Public Relations
CMO	Chief Medical Officer
COIP	Community oriented intervention programme
CONSORT	Consolidated standards of reporting trials
CT	Computerised tomography
CVD	Cardiovascular disease

DALYs	Disability adjusted life years
DCSF	Department for Children Schools and Families
DCMS	Department of Culture, Media and Sport
DEBQ	Dutch Eating Behaviour Questionnaire
DEXA	Dual-energy x-ray absorptiometry
DfES	Department of Education and Skills
DH	Department of Health
DVD	Digital versatile disc
FBBT	Family-based behavioural treatment
FDF	Food and Drink Federation
GOALS	Getting Our Active Lifestyles Started
GP	General Practitioner
HAPA	Health Action Process Model
HDL	High density lipoprotein
HeLP	Healthy lifestyles programme
HIKCUPS	Hunter and Illawarra Kids Challenge Using Parent Support
HM	Her Majesty
HSE	Health Survey for England
IASO	International Association for the Study of Obesity
ICEBeRG	The Improved Clinical Effectiveness through Behavioural Research Group
IDEFICS	Identification and prevention of dietary- and lifestyle-induced health effects in children and infants
IDM	Interactive domain model
IM	Intervention mapping
IOTF	International Obesity Task Force
IVR	Interactive voice response

LDL	Low density lipoprotein
LEAP	Live, Eat and Play
MEND	Mind, exercise, nutrition … do it!
MRC	Medical Research Council
MRI	Magnetic resonance imaging
NAO	National Audit Office
NCMP	National Child Measurement Programme
NHF-NRG	Netherlands Heart Foundation – Netherlands research programme weight gain prevention
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NOO	National Obesity Observatory
NPT	Normalisation Process Theory
NRES	National Research Ethics Service
NRG-DOiT	Netherlands research programme weight gain prevention – Dutch obesity intervention in teenagers
PAC-Q	Physical Activity Questionnaire – Older Children
PC	Personal computer
PCT	Primary Care Trust
PEACH	Parenting Eating and Activity for Child Health
PedsQL	Pediatric Quality of Life Inventory
PO	Performance objective
PRECEDE	Predisposing, Reinforcing, and Enabling Constructs in Educational Diagnosis and Evaluation
PROCEED	Policy, Regulatory, and Organisational Constructs in Educational and Environmental Development
PSA	Public Service Agreement

RCPCH	Royal College of Paediatrics and Child Health
RCT	Randomised controlled trial
SACN	Scientific Advisory Committee on Nutrition
SCOTT	Scottish Childhood Overweight Treatment Trial
SD	Standard deviation
SDQ	Strengths and Difficulties Questionnaire
SDS	Standard deviation score
SEF	Standard evaluation framework
SES	Rosenberg Self-esteem Scale
SHA	Strategic Health Authority
SIGN	Scottish Intercollegiate Guideline Network
SPPC	Self-perception profile for children
TTM	Transtheoretical model
TV	Television
UK	United Kingdom
UK90	British 1990 growth reference charts
UKPHA	United Kingdom Public Health Association
USA	United States of America
WCC	World Class Commissioning
WHO	World Health Organisation
WLC	Waiting list control

Appendix 44 Example week from the Y W8? Manual

Week 3 – Children and Parents Session

Keeping the Balance

Aim of the session

To learn that food is energy for our bodies and we need to keep in balance
To have an introduction to the Eatwell Plate
To understand the Traffic Light System and how to apply it

Objectives of the session

- To understand that we need to balance our energy intake with energy expended
- To gain an understanding of the different food groups and the foods these contain
- To have an understanding of the importance of the different food groups to our body and growing healthily
- To have had an introduction to the Traffic Light System guide to making food choices

Y W8? Mentors essential reading

Y W8? is about learning to be healthy. Learning to balance healthy eating with regular physical activity is beneficial to all, regardless of BMI. Reinforcing this to families on the programme is very important. Many of the parents attending with their child will have other children at home who are not overweight. A common barrier parents voice in making changes at home is that they don't feel it is fair on their other children. Emphasizing the importance of the whole family beginning to live healthily can assist in convincing parents to make changes at home for all, not just those that show signs of being overweight.

In order to control their weight individuals need to understand the concept of energy balance. We use the term energy to mean calories. What you eat and drink is energy in, what you burn through physical activity and body functions is energy out. We all burn a certain amount of calories in our normal everyday lives as our body burns energy to function. However, it is important to understand that people who are more physically active burn more calories than those that are sedentary or less active.

Using the terms energy in and energy out, if;

Energy in = Energy out	Weight stays the same
Energy in > Energy out	Weight gain
Energy in < Energy out	Weight loss

Energy in and energy out don't need to balance exactly every day. It's the balance over time that determines whether individuals maintain a healthy weight in the long run. Children need energy to grow properly so energy balance in children happens when the amount of energy in and energy out supports natural growth without promoting excess weight gain.

A healthy diet is based on whole grains, fruits, vegetables, milk and meat or meat substitutes. It is a diet that includes a wide variety of foods that all the family can enjoy. Unfortunately, choosing these foods has become increasingly difficult in recent years. There are so many choices and so much information on what to eat and what not to eat that it is easy to become confused. The nutrition sessions at Y W8? aim to give the families basic nutrition knowledge with practical ideas that they can adopt in their home life.

Just as there are recommendations for a healthy weight, there are recommendations for a healthy diet. At Y W8? we base the nutrition education on the Eatwell plate from the Food Standards Agency (FSA). The Eatwell plate makes healthy eating easier to understand by showing the types and proportions of foods we need to have a healthy and well balanced diet. The plate shows how much of what you eat should come from each food group. This includes everything you eat during the day, including snacks.

Fruit and vegetables

You can see from the way the plate has been divided up that fruit and vegetables should make up about one third of the food we eat each day. In real terms we should aim to eat at least five portions of fruit and vegetables everyday. Fresh, frozen, tinned (in their own juice) and dried count and it is important to eat a variety. We use the phrase 'Eat a rainbow' to refer to the recommendation that we should eat a variety of fruit and vegetables and to ensure we are doing this we should try to eat lots of different coloured fruit and vegetables.

Remember that potatoes don't count because they are starchy food, and only 1 glass of fruit juice a day counts as a portion (this is because when juice is extracted from the whole fruit or vegetable, it reduces the fibre content and releases a type of sugar from the fruit or vegetable that can damage teeth, especially if you drink it frequently).

It is important to eat the recommended amount of fruit and vegetables as they are a good source of vitamins and minerals and are very low in fat. They are also a great source of fibre which keeps the digestive system healthy. There is increasing evidence to show that people who eat lots of fruit and vegetables are less likely to develop chronic diseases such as coronary heart disease and some cancers.

Pulses, including baked beans, lentils, peas, runner beans, chick peas, kidney beans, etc, count as one of the variety of fruit and vegetables we should be aiming to eat each day. Like fruit juice, pulses can only make up a maximum of one portion of your fruit and vegetables a day. This is because we need to eat a variety of fruit and vegetables to make sure we get all the important nutrients we need.

Breads, rice, potatoes, pasta

Starchy foods such as bread, rice, pasta and potatoes should make up about a third of the food we eat. Starchy foods are a good source of energy and the main source of a range of nutrients in our diet. As well as starch, these foods contain fibre, calcium, iron and B vitamins.

Wholegrain varieties are the best choice as they are rich in fibre. We also digest wholegrain foods more slowly so they keep us feeling fuller for longer. At Y W8? we talk about wholegrain / wholemeal varieties as being 'log' fuel (as we discussed in week 2). Examples include; wholegrain bread, wholemeal bread, brown rice, wholemeal pasta and wholegrain breakfast cereals.

Milk and dairy foods

This group contains milk and other dairy products such as cheese, yoghurt and fromage frais. These foods are a great source of protein and vitamins A and B12. They are also an important source of calcium which helps to keep our bones strong. The calcium in dairy foods is easy for the body to absorb.

Milk and dairy products are an important part of a child's diet. They are a good source of energy and protein, and contain a wide range of vitamins and minerals, particularly calcium, which growing children and young people need to build healthy bones and teeth.

Meat, fish, eggs, beans and other non-dairy sources of protein

All of these foods are a good source of protein. Protein is required for growth, repair and maintenance of the body. It is needed to build our muscles and other tissues in the body. Protein also gives us energy, keeps our body working properly and helps protect us from infection.

Meat is a good source of protein and vitamins and minerals such as iron, selenium, zinc and B vitamins. It is one of the main sources of vitamin B12, which is only found in foods from animals, such as meat and milk.

It is recommended that we eat at least 2 portions of fish a week including one type of oily fish. Oily fish includes; salmon, trout, mackerel, herring, sardines and fresh tuna. Fish and shellfish are rich in protein and minerals, and oily fish is rich in omega 3 fatty acids.

Eggs, pulses, nuts and seeds are all good sources of protein. Eggs are a good choice as part of a healthy balanced diet and are a good source of protein and some vitamins.

Pulses include beans, lentils and peas. They are a low-fat source of protein, fibre, vitamins and minerals and they count as a portion of fruit and vegetables (see above).

Nuts are high in fibre, rich in a wide range of vitamins and minerals and a good source of protein (which is important for vegetarians). They can be a good alternative to snacks high in saturated fat. They are a good source of monounsaturated fat, which can help reduce the amount of cholesterol in our blood. They also contain other unsaturated fats called 'essential fatty acids', which the body needs for good health. However, nuts are also high in fat, so it's a good idea not to eat too many of them, and try to avoid salted nuts because they are very high in salt.

Seeds contain protein, fibre, vitamins and minerals. They also add texture and flavour to various dishes and make a healthy snack. Examples of seeds include; sunflower, pumpkin, sesame and poppy.

Foods and drinks high in fat and/or sugar

This is the smallest section on the Eatwell plate and only a small amount of our diet should come from this group. We cover both fats and sugars in later Y W8? sessions. For this session it is important that families understand the foods that are in this group and that we should eat only a small amount from this group each day.

Foods and drinks in this group that are high in fat include; margarine, butter, cooking oils, mayonnaise, cream, salad dressing, gravy and crisps.

Foods and drinks in this group that are high in sugars include; fizzy drinks, energy drinks, sweets, jam, sugar, cakes, pastries, biscuits and puddings.

The Traffic Light System

At Y W8? we use the Traffic Light System to help families understand the best foods to eat for a healthy diet. This system has been used successfully on a number of weight management programmes in the UK and in the United States. The system categorizes foods into the colours of the traffic light; red, amber and green, based on their calorie and nutrient content. By following this simple guide it is hoped that families will make healthy choices and change their food preferences as well as energy and nutrient intake.

Green foods are everyday foods. They are the lowest in fat and sugar, and relatively low in calories. They are also "nutrient dense," which means they are rich in vitamins,

minerals, and other nutrients important to health. Green means – 'go for it!' because we should aim to eat more of these foods.

Amber foods are higher in fat, added sugar and calories than green foods and should be eaten less often. Foods in the amber section are 'approach with caution' foods, they should be chosen carefully.

Red foods are the highest in fat and added sugar. They are "calorie-dense" (high in calories), and many are low in nutrients as well. Red foods should be eaten once in a while or on special occasions. They should also be eaten in small portions. Foods in the red section are 'stop – and think' foods.

In summary;

Green Foods - Eat almost anytime as part of a balanced diet
Amber Foods - Eat sometimes, at most several times a week
Red Foods - Eat only once in a while or for special occasions.

The Traffic Light Handout lists the food groups and divides the foods within the food groups in to red, amber and green foods. It is, however, impossible to list every single food that a family might choose or be exposed to. When families are unsure they should be encouraged to use their Food Shopping Card they were given in week 2. This card uses the colours red, amber and green to denote high, medium and low levels of sugar, fats, saturates and salt in food. By reading the food label and using the card the families should be able to decide if the food they are assessing is a healthy choice.

Familiarising the group with the concept of red, amber and green is also very important because the FSA recommends the use of the traffic light system for labelling on the front of packs. By getting families used to colours and what they symbolise they will also be able to make better choices at the supermarket because they will be familiar with the meaning of the colours.

Session outline

Time	Activity	Content	Equipment / Handouts
10 mins	Quizzes	• Lay out the quizzes and pens for families to help themselves • Ask each child and parent to write their name on a label (if required) • Y W8? Mentor and activity instructor to chat to the families as they arrive; check how they are progressing, any questions, etc	Register Name labels Felt-tip pens Quiz – Fact or Fiction Quiz - KTB
5 mins	Welcome, introduction and recap	• Welcome the families • Introduce the session; Keeping the Balance • Recap last week we talked about healthy breakfasts • Ask the group; who managed to achieve the breakfast challenge? What changes did they make? • Recap log and paper foods	Challenge chart Log Paper
10 mins	Fact or Fiction and Keeping the Balance (KTB) quiz	• Go through the answers to the Fact or Fiction quiz • Go through the answers to the Keeping the Balance Quiz	Quiz - Fact or Fiction answers Blue tac Quiz answers – A, B, C and D Quiz – KTBQuiz answers
10 mins	Energy balance	• Introduce the terms energy balance, energy in and energy out • Remind the group of the rocket analogy last week and reinforce that food is fuel • Use the ping pong balls to demonstrate what happens when we overeat • Use the envelopes to show how we store food	Flip-chart Flip-chart pens Ping pong balls x 10 Transparent container A5 envelopes x 2
5 mins	Introduction to the eatwell plate	• Introduce the Eatwell plate using a food mat • Explain that the Eatwell plate shows us the types and proportions of foods we need to have a healthy and well balanced diet • The plate shows how much of what you eat should come from each food group. This includes everything eaten during the day, including snacks	Food mat Child-Handout Parent-Handout
10 mins	Food groups and their functions	• Introduce the 5 food groups • Split the families into 3 groups and ask the groups to put the replica foods into the 5 food groups on the food mats • Discuss where they have put the foods and make adjustments as necessary • Talk through the 5 food groups and explain why we need them	Food mats x 3 Selection of replica foods / pictures of foods x 3 Child-Handout Parent-Handout
10 mins	Introduction to the traffic light system	• Introduce the Traffic Light System and the meaning of red, amber and green foods • Following this simple guide will help families to make healthy choices • Use the Traffic Light handout to explain which foods are in which group • Encourage families to use their Food Shopping card from week 2 to decide on the 'colour' of other foods not listed	Traffic light-Handout

Equipment required

Register
Name labels
Felt-tip pens
Flip-chart
Flip-chart pens
Quiz answers – A, B, C and D (to stick up on the walls)
Blue Tac
Log
Paper
Ping pong balls x 10
Transparent container (vase, etc)
A5 envelopes x 2
Food mats x 3
Selection of replica foods / pictures of foods x 3
Y W8? Handouts –

- Quiz – Fact or Fiction (1 per child)
- Quiz – Fact or Fiction answers (1 per child)
- Quiz – KTBQuiz (1 per child + 1 per parent)
- Quiz – KTBQuiz answers (1 per child + 1 per parent)
- Child-Handout (1 per child)
- Parent-Handout (1 per parent)
- Traffic Light–Handout (1 per child + 1 per parent)

Feedback sheet
Challenge chart

Detailed session plan

Welcome, introduction and recap

"Welcome back. Good to see you all. In today's session we are going to talk more about nutrition and having a healthy, balanced diet. Before we do that who can remember what we talked about last week? (Invite answers from the group). *That's right, we talked about having a healthy breakfast and the difference between log and paper foods.* (Amend wording as necessary based on the group's responses). *So how did you get on with your challenge to eat a healthy breakfast everyday? What changes did you make?"*

Allow individuals to tell the group how they got on. Question them as to what they had for breakfast and if this was a change from normal. Ask the group if they can remember the difference between log and paper foods. Ask them if they have changed any of their paper food, or if they are eating more log food. Remind the group about how log and paper foods burn if necessary.

Fact or Fiction and Keeping the Balance (KTB) quiz

Go through the answers to the Fact or Fiction quiz. There is no need to do this as a walking quiz.

Next go through the answers to the Keeping The Balance quiz as a walking quiz. The 'A', 'B', 'C' and 'D' quiz answers should be stuck on the walls of the room.

"We are now going to do a walking quiz. Everyone should have had chance to try and answer the Keeping the Balance quiz at the start of the session (hold up the Keeping the Balance quiz handout)*. In the quiz there are 6 questions and there are 4 different answers labelled A, B, C and D. I am going to read out the questions one by one. If you think the answer to the question is A then stand by the poster with A on it. If you think the answer is B then stand by the poster with B on it. Poster C if you think the answer is C and poster D if you think the answer is D.* (Point out the posters as you do this)*. OK here is the first question; how many portions of fruit and vegetables should we eat each day? A is 3 portions, B is 4 portions, C is 5 portions and D is 6 portions. Stand by the poster you think is correct. The correct answer is C, 5 portions. Everyone standing by C well done, everyone else better luck with this next question ….."* Continue in the same manner through all 6 questions.

Ask the group to sit back down when the quiz has finished.

Energy balance

"We are now going to talk about energy balance. Everything you eat and drink is energy in and what you burn through physical activity and body functions is energy out. Everyone OK with those terms? (Check understanding and write the terms on the flip-chart and repeat if necessary)*. People who are more physically active or do more exercise burn more energy than those that are less active. Balancing our energy in and energy out over time helps us to keep healthy."*

"Remember last week we imagined ourselves being rockets and the food and drink we had was fuel. If the rocket has the right amount of fuel then it can take off and get to the moon. If the rocket doesn't have enough fuel then it won't be able to take off, and if it has too much fuel on board then it will be too heavy to take off."

"We also need to make sure we have the right amount of energy. I want you to imagine this is your body burning energy. (Hold up the transparent container). *Now imagine that this is the food you eat.* (Hold up the ping pong balls). *When we get up in the morning what do we do?* (Answer is eat breakfast). *That's right we have some healthy log fuel for breakfast.* (Put 3 ping pong balls in to the container). *We then get ready and walk to school.* (Take 1 ping pong ball out of the container). *We are burning energy through walking so we are using up some of our fuel. We then get to school and sit in lessons. At break we have a snack.* (Add 2 ping pong balls to the container), *but we also run around with our friends*. (Remove 1 of the ping pong balls). *We then go back in to class."*

"At lunch we have our school dinner (add 3 ping pong balls) *and our friend doesn't want their pudding so we have that as well* (add another ping pong ball). *We then go out in the playground and play for a while* (remove 1 ping pong ball). *Then we have our afternoon lessons. We walk home from school* (remove 1 ping pong ball) *and when we get home mum is still at work so we raid the biscuit tin and sit in front of the TV to watch our favourite programmes* (add 3 ping pong balls – the container should be getting full now)."

"*Mum comes home from work and says – 'you must be starving you can't have had anything to eat since lunchtime I'll make you a lovely tea' – which you eat all up.* (Try to add 4 more ping pong balls – the container should be overflowing). *Now look what's happened. Our body is full of energy and because we didn't do any activity we haven't burnt anymore off. What shall we do with the rest of the balls? I know we'll put them in these envelopes.* (Put the spare ping pong balls into the envelopes). *We will have to store the extra energy in these. Can you see? If your body has too much fuel it needs to grow bigger too quickly and although you are getting taller your body can't keep up with the extra fuel so we have to store it."*

Ask the group; *"How do you think we feel when our envelopes get too full or we're storing too much energy?"*

Write the answers on the flip-chart. Try to prompt the group to give answers about eating and activity behaviour rather than answers just about weight. Example answers include:

- Unhealthy
- Unfit
- Too heavy
- Get out of breathe
- Can't keep up with friends
- Clothes too tight
- Unhappy

"Let's imagine now we are in balance. The amount of energy we take in balances the amount of energy we burn up. How do we feel when we are in balance?"

Again write the answers on the flip-chart. Try to prompt the group to give answers about eating and activity behaviour rather than answers just about weight. Example answers include:

- Healthy
- Fit
- Healthy weight
- Can keep up with friends
- Happy

"That's right. We want to be like the rocket with the right amount of fuel on board so we can take off and get to the moon or do all the things we want to do and be healthy. Are there any questions on energy balance?"

Answer questions as necessary.

Introduction to the Eatwell plate

Hold up the food mat and ask the group if they have seen it before. Many of the children will recognise the Eatwell plate as it is taught at school. Many parents won't have seen it before.

"The Eatwell plate is a guide to help you choose what and how much to eat from each food group to have a healthy, balanced diet. Eating a balance means that there are no forbidden foods at Y W8? but some foods are better for us than others and this is shown by the plate. The plate shows how much of what you eat should come from each food group. This includes everything eaten during the day, including snacks."

Handout the child and parent handouts.

Food groups and their functions

"There are 5 food groups; (point to the groups on the mat as you introduce them) *fruit and vegetables; bread, rice, potatoes and pasta; meat, fish, eggs and beans; milk and dairy foods and foods and drinks high in fat and / or sugar. Foods from the largest groups should be eaten most often, that's fruit and vegetables and bread, rice, potatoes and pasta. Foods from the smaller groups should be eaten less often, that's meat, fish, eggs and beans and milk and dairy. Foods from the smallest group should be eaten rarely; that's foods and drinks high in fat and / or sugar."*

Split the families into 3 groups and give each group a food mat and a selection of replica foods or pictures of foods. Ask the groups to put the foods into the 5 food groups on the food mats. They might need to discuss where to put some foods and decide between the group. The Y W8? Mentor should circulate round the groups and check they have got the foods placed correctly. Ensure potatoes, breakfast cereals, nuts, eggs, etc have been put in the correct group as these are often placed incorrectly.

If possible use a composite food like pizza to explain that dishes containing more than one food can also fit into the model. For example, a pizza has a dough base with toppings. The dough base is a starchy food that fits in the bread section. If the pizza is homemade the topping could be made with reduced fat cheese, from the dairy section, and more tomato and vegetables (from the fruit and vegetables section).

Draw the group back together and use a combination of questioning and prompting to explain why we need the different food groups. There is room for them to write this in their handout if they wish.

Breads, rice, potatoes, pasta

- Fill us up foods / energy giving
- Eat log foods to give us lasting energy throughout the day
- Good source of fibre which helps us go to the toilet regularly
- Log foods are wholegrain, wholemeal varieties

Fruit and vegetables

- High in fibre
- Contain lots of vitamins and minerals
- Keep us healthy

Meat, fish, eggs, beans

- Contain lots of protein to help us grow
- Protein builds our muscles

Milk and dairy foods

- Contain protein
- Provides calcium to keep our teeth healthy and our bones strong

Foods and drinks high in fat and / or sugar

- The right type of fat can give us essential nutrients but we have to be careful we choose the right types of fat

Introduction to the Traffic Light System

"At Y W8? we don't think of foods as good or bad, we prefer to talk about foods we should eat more of and foods we should eat less of. To help you begin to make healthy choices and eat a healthy balance diet we have devised a traffic light system. (Give out the Traffic light handout). *You can see that we have divided foods into the colours of a traffic light, red, amber and green."*

"Green foods are the lowest in fat and sugar, they are healthy for us. Green means 'go for it!' because we should aim to eat these foods anytime as part of a balanced diet. You can see that lots of fruit and veg, wholegrain and wholemeal foods are in the green section."

"Amber foods are higher in fat and sugar than green foods and should be eaten less often, at most several times a week. Amber foods are 'approach with caution'. Choose them carefully."

"Red foods are the highest in fat and sugar. They are 'stop and think' foods. Red foods should only be eaten once in a while or on special occasions. The red section includes our favourite snacks and treats."

"Following this simple guide will help you to make healthy choices. We have tried to include lots of common foods on this list. However, it's impossible to include everything that you might want to eat. If you are unsure then use your Food Shopping Card you were given last week. This card uses the colours red, amber and green to tell you if a food is high, medium or low in sugar, fats, saturates and salt. By reading the food label and using the card you should be able to decide if the food you are looking at is a healthy choice. Are there any questions about this?"

Answer questions as necessary.

Bring the session to a close by asking the families to pack away the replica food / pictures of food and the food mats.

The children then go with the physical activity instructor to have their exercise session.

Week 3 – Parents Session

External and Internal Triggers

Aim of the session

To introduce the parents to the concept of triggers that cause unhealthy and healthy behaviour
To be able to identify triggers that promote unhealthy and healthy choices

Objectives of the session

- To explore the different types of triggers that cause children to eat unhealthily or be inactive
- To identify external triggers for their child to be inactive or eat unhealthily and identify ways to prevent or manage the trigger
- To discuss the four types of internal triggers and learn strategies for dealing with these
- To understand how new triggers can be introduced to help children make healthy choices

Y W8? Mentors essential reading

Triggers

A trigger is something that results in a certain behaviour. For example, walking past the fridge may result in the urge to grab a snack, or having a cup of tea may trigger the need for a biscuit. One trigger can also trigger something else. Walking past a pub may trigger an urge for a drink and this drink may trigger the urge for a cigarette. Avoiding the pub may help the individual to give up smoking. Triggers that cause us to avoid doing something healthy, or do something unhealthy, need to be reduced.

There are 2 types of triggers; external and internal.

External

External triggers are things in the environment that lead us to act in a certain way. In the above example, walking past the fridge may result in the urge to grab a snack. The fridge is the external trigger. External triggers may be embedded in to family routines or might be actual people. Grandparents can often be the cause of unhealthy eating behaviour and might be resistant to change.

Other examples of external triggers include being somewhere that makes you want to eat, for example at a party or the cinema. The sight or smell of food can be a very powerful trigger for many people even though they are not hungry. The TV, computer and Playstation are all external triggers for inactivity.

It is important for parents to be able to identify triggers that cause unhealthy behaviours because then these triggers can be reduced or, hopefully, removed. Triggers can also

cause healthy behaviours; triggers are certainly not always a negative thing. For example, having a fruit bowl on show. If parents are taught what triggers healthy habits then they can put these in place. In this way, the environment of the child can be gradually changed without the child having to be constantly told what to do or continually being told 'no'. This subtle change over time will reduce conflict whilst ensuring healthy habits are encouraged and supported.

Internal

Internal triggers are thoughts or feelings that cause you to behave in a certain way. These triggers need to be identified, understood and tackled if children are going to be able to adopt a healthier lifestyle. The role of internal triggers is complex and dealing with them can often be far more difficult than removing an external trigger.

There are 4 main internal triggers;

- Hunger
- Cravings
- Unhelpful thoughts
- Negative feelings (e.g. sadness, stress, boredom)

Hunger is the mechanism our bodies use to tell us that we require energy. As we discussed in the first session, we get hungry when our blood sugar levels drop too low. If we ignore hunger it can cause us to overeat or eat the wrong types of food – such as paper foods. Active children, or children who have finished school and had their school lunch at around 12.30pm, will often be hungry. This can result in them snacking on high sugar or junk foods. Parents need to plan and ensure that there are healthy snacks at home or with them when they pick them up from their activity class. Children who refuse a healthy snack probably aren't hungry.

Cravings are the intense desire to eat a certain food even when we are not hungry. Cravings can often drive us to eat in between meals. Our sense of hunger gets stronger and stronger whilst our craving can be ignored and will go away after about 20 minutes. There are no harmful effects from ignoring cravings.

Unhelpful thoughts are thoughts that affect the way we behave and influence whether we change or not. Helpful thoughts are positive and support us to make and maintain changes. Unhelpful thoughts make it difficult for parents and children to sustain their healthy lifestyle. It is very important that families think positively about eating and being active and ignore negative unhelpful thoughts.

Negative feelings about ourselves can have a detrimental affect on making healthy changes. They can lead us to overeat or not want to be active. There are many negative feelings – a few common ones are:

- Sadness – Food is often used to relieve feelings of sadness. It makes us feel better, but only for a short amount of time
- Stress – Food is often used to calm us or stop us feeling anxious. This can easily lead to excessive weight gain

- Boredom – This is a very common negative feeling for both children and adults. Children want to eat when they have nothing to do

Dealing with internal triggers can be much more challenging than dealing with external triggers. However, some of the strategies used to deal with external triggers can also be used to deal with internal ones. Parents may have their own issues with food and internal triggers which they might focus on in this session. Helping them to solve how they can manage these triggers can be helpful in helping them to understand how they can help their children, and helps them to become a positive role model for their child A parent identifying their own triggers is also really important as children will observe their parents reaction to triggers and copy the behaviour.

There may be issues raised during this session that you are unable or unqualified to deal with. Although rare, some families may require specialist input from worker experienced in child mental health or eating problems. If required, contact your local service to refer the family on.

Session outline

Time	Activity	Content	Equipment / Handouts
10 mins	Welcome and review of role modelling and monitoring	• Ask the parents if they have achieved their role modelling behaviour they committed to last week • Ask the group if they have monitored either themselves of their child during the week and, if so, what they learnt / changed	
10 mins	Introduction to external triggers	• Introduce external triggers and how they affect our behaviour • Parents to visualise the triggers in their own home • Ask the group to give examples of external triggers that cause their child to eat unhealthy food • Ask the group to give examples of external triggers that cause their child to be inactive	Parent-Handout Flip-chart Flip-chart pens
10 mins	External triggers activity	• Divide the parents into pairs and give them each 1 trigger that causes unhealthy eating and 1 trigger that causes inactivity • Ask them to come up with ways to prevent or manage the unhealthy eating and inactivity triggers • Ask them to come up with a healthy trigger that could replace each unhealthy trigger • Ask parents to feedback to the group	Parent-Handout
5 mins	Introduction to internal triggers	• Introduce internal triggers and how they affect our behaviour • Introduce the 4 types of internal triggers • Ask the group to give examples of their child's unhealthy behaviour caused by internal triggers	Parent-Handout Flip-chart Flip-chart pens
10 mins	Internal triggers activity	• Divide the parents into 4 groups with a piece of flip-chart paper and pens. Give each group one of the types of internal triggers. • For their internal trigger, ask the group to list ideas of how they can manage or prevent the trigger. • Ask parents to feedback to the group	Parent-Handout Flip-chart Flip-chart pens
5 mins	Conclusion	• In this session we have talked about external and internal triggers • We have explored how to identify unhealthy triggers in our family life and explored how to introduce healthy triggers	
		CHILDREN RETURN FROM THEIR EXERCISE SESSION	
10 mins	Re-cap and challenge setting	• Thank the families for coming to the session • Re-cap that food is a fuel and we need to remain in balance • Re-cap the food groups • Introduce next weeks topic – Eat Right, Stay Bright • Ask for feedback to be written on the feedback sheet • Introduce the challenge for the week – Do 30 mins of activity every day	Felt-tip pens Feedback sheet Challenge chart

Equipment required

In addition to the equipment you will have for the children and parents session you will need:

Y W8? Handouts –

- Parent-Handout (1 per parent)

Detailed session plan

Welcome and review of role modelling and monitoring

"Welcome to our second parents session. Has everyone had a good week? Last week we talked about role modelling and monitoring and you all committed to a role modelling behaviour. You should have written it in your handout from last week if you need reminding. I did say last week that I was going to ask you if you have achieved it so let's go round the group and just be honest and tell us how you got on. Let's start here (nominate a parent who looks eager)."

Allow each parent to tell the group how they got on. Praise those that have achieved it and if parents have struggled allow other parents in the group to offer possible solutions they can try.

Ask the group if they have monitored either themselves of their child during the week and, if so, what they learnt / changed.

Introduction to external triggers

"Today we are going to talk about triggers. A trigger is something that results in a certain behaviour. We are surrounded by triggers every minute of everyday. They cause us to act how we act, to behave how we behave, without even realising it. To help your child to get healthier you need to identify the triggers which cause them to over eat, eat too much unhealthy food or be inactive and replace them with triggers that cause them to be healthy."

"Firstly, we are going to talk about external triggers. These are things all around us. For example, walking past the fridge may trigger opening the fridge and having an unhealthy snack. Seeing an open bag of Minstrels on the table may trigger you to have one. Having a cup of tea may trigger you to have a biscuit. Walking past the newsagents may trigger buying some sweets or crisps. Seeing the Playstation control on the floor may trigger your child to play a game. You can think of some external triggers as temptations – and lots if us can't resist temptation! The best way of dealing with it is to avoid the temptation all together, and the best way of dealing with external triggers is to avoid them, and replace them with triggers for healthy behaviour. What is a trigger for one child will not be the same as triggers for another child. Identifying the triggers for your own child is really important and is the first step in being able to remove them and replace them with healthy triggers. So do you understand what I mean by external triggers?"

Ask parents to visualise the triggers in their own home by talking through the following example;

"I want you to try and recognise the triggers in your home for healthy and unhealthy behaviours. Sit back and close your eyes. Imagine walking up to your front door and opening the door. What do you see? Are there shoes and trainers, coats and jackets ready to put on? Turn into your lounge or living room – what do you see? Is there a big TV turned on, with lots of DVD's underneath, a Playstation with the controller ready to use? Is the TV off and other activities around? Go through to the kitchen. Is there a fruit bowl on display? Are there treats and snacks enticing you? Open the fridge door – what do you see? Is there healthy snacks ready to munch on? Is it full of ready meals? Look out in to the garden. Is there sports equipment ready to play with? Maybe a trampoline? What about in the garage or shed? Are the bikes ready to use or have they got a puncture and haven't been fixed for ages?"

Check the groups understanding of the triggers you are trying to get them to recognise.

Ask the group to give examples of external triggers that cause their child to eat unhealthy food. Write the answers on the flip-chart under the heading of 'Triggers for unhealthy eating'. You may need to prompt the group.

Then ask the group to give examples of external triggers that cause their child to be inactive. Again, write them on the flip-chart under the heading of 'Triggers for inactivity'. The group may need some ideas to start with.

For each question try and have 6 triggers as we will be using them in the next activity.

Example answers include:

Triggers for unhealthy eating

- Habit e.g. having a biscuit every time you have a cup of tea
- Having sweets, chocolate and crisps in the cupboards at home
- Seeing other people eating unhealthy foods
- Eating in front of the TV
- Watching unhealthy cookery programmes on the TV
- School dinners
- Having spare money to spend at break or at the vending machine
- Not having healthy alternatives around
- Not planning meals and mealtimes
- Going to do the shopping at the supermarket whilst hungry
- Trips to other people's houses e.g. grandparents

Triggers for inactivity

- Television
- Computer games / Internet
- Playstation / X Box
- Weather
- Worried about playing out in the neighbourhood

- Inactive parents or role models
- Not having anything planned
- Embarrassment about size
- Can't afford exercise sessions
- No-one to play with

External triggers activity

"To help us think how we can cope with all these triggers we are surrounded by and to think about how you can make changes to reduce the triggers around your child we are going to do an activity." Handout the parents handouts.

Divide the parents into pairs and give them each 1 trigger that causes unhealthy eating and 1 trigger that causes inactivity (if you have fewer parents you may want to give some more than 2 triggers). Make sure each pair has an unhealthy eating trigger and an inactivity trigger so they can practice with both types.
For the first part of the activity ask the parents to come up with at least 2 ways to prevent or manage the unhealthy eating or inactivity triggers. Parents can record their answers to this activity in their handout on page 3.

For example;

Triggers for unhealthy eating

- Having sweets, chocolate and crisps in the cupboards at home
  Ways to prevent / manage =
  Don't buy high fat / high sugar snack food at all
  Set a rule that the child must ask you before they are allowed to take this type of food
  Don't have this type of food visible in the home

- Having spare money to spend at break or at the vending machine
  Ways to prevent / manage =
  Limit the amount of money your child has each day – give them exactly the right amount of money for what they need
  Ask your child to take a healthy packed lunch to school
  Create a 'bank' for your child to put the money in and allow them to spend it on a healthy treat

- Not having healthy alternatives around
  Ways to prevent / manage =
  Make sure there is a fruit bowl where the child can see it
  Have chopped veg and healthy dip in the fridge for when they need a snack
  Have only healthy snacks in the house

Triggers for inactivity

- Television / Computer games / Internet / Playstation / X Box
  Ways to prevent / manage =

Have set time for these activities which must be kept to
Leave other toys / activities around as alternatives
Have planned activities or groups to attend in the evenings
Only turn on the TV to watch favourite shows

- Inactive parents or role models
  Ways to prevent / manage =
  Join a local sports centre together
  Play games in the evening which don't involve 'screen time'
  Challenge each other to train for a special event
  Try something new together

Ask the parents to feedback their ideas to the group. If parents are struggling for ideas then ask other parents to help out.

Then ask the parents in their pairs to come up with a healthy trigger that could replace each unhealthy trigger they have been given. Again their answers can be recorded in their handout on page 4.

Examples of triggers for healthy behaviours include;

Triggers for healthy eating

- Having healthy foods visible around the house e.g. a fruit bowl
- Having chopped veg and healthy dip in the fridge for when they need a snack
- Eating together as a family at the table with the TV off
- Seeing other members of their family eating healthy foods
- Seeing their role models eating healthy foods
- Encouraging children to take part in healthy food preparation
- Letting children serve themselves at the table (assists in portion control)
- Not having unhealthy foods in the house
- Encouraging children to make healthy choices in the supermarket
- Understanding why it is important to eat healthily
- Praising children when they eat healthily

Triggers for activity

- Playing with your child
- Building activity into your normal life e.g. walking to school
- Having sports and activity equipment at home to use e.g. bike, balls
- Limiting 'screen time'
- Joining a sports club or enrolling in swimming lessons, etc
- Being active with family / friends
- Having a plan of activity to do when the weather is bad
- Have music on at home so the first action isn't turn on the TV

Again, ask the parents to feedback their ideas to the group. If parents are struggling for ideas then ask other parents to help out.

Introduction to internal triggers

"In the second part of this session we are going to talk about internal triggers. Internal triggers are thoughts or feelings that cause you to behave in a certain way. These internal triggers need to be identified, understood and tackled if children are going to be able to adopt a healthier lifestyle. The role of internal triggers is complex and dealing with them can often be far more difficult than removing an external trigger. However, there are some simple strategies that can be used to help with managing internal triggers."

"There are 4 types of internal triggers; hunger, cravings, unhelpful thoughts and negative feelings such as stress and boredom. (Write the 4 types on the flip-chart). *I'm going to explain each one in turn."*

"Hunger is how our bodies tell us that we require energy. In the session earlier we talked about food being a fuel and when we feel hungry our body is telling us it needs refuelling. However, many people override their hunger sensations by eating when they aren't hungry or skipping meals. This can lead to us overeating. If we ignore hunger it can cause us to overeat or eat the wrong types of food – such as paper foods. Children who have finished school and had their school lunch at around 12.30pm, will often be hungry. This can result in them snacking on high sugar or junk foods."

"Cravings are described as the desire to eat something even when we are not hungry. Can everyone relate to that? Cravings can often drive us to eat in between meals. However, our sense of hunger gets stronger and stronger whilst our craving can be ignored and will go away after about 20 minutes. There are no harmful effects from ignoring cravings."

"Unhelpful thoughts make it difficult for us to make healthy changes and stick to them. If you feel negative towards yourself or what you are trying to achieve then you are not likely to be successful. For example, if you think you have done badly at something then you will feel fed up and are not likely to try again. Helpful thoughts are positive and support us to make and maintain changes. So, if you think you have done well at something then you will feel happy and are more likely to repeat what you did. It is really important that you help your children to think positively about eating healthily and getting active and ignore negative unhelpful thoughts."

"The last internal trigger we are going to learn about is negative feelings. Again these feelings can make it difficult for make healthy changes. They can make us overeat or not want to be active. Can anyone think of any examples of negative feelings?"

List their ideas on the flip-chart.

Example answers include:

- Sadness / Unhappiness
- Stress
- Boredom
- Depression
- Anger

- Worry

The group may require prompting. Make sure you list sadness, unhappiness and boredom at a minimum. Give a bit more detail about sadness, unhappiness and boredom.

"Feelings of sadness, or unhappiness, can often make us want to eat to make ourselves feel better. This is called comfort eating. The food does make us feel better but only for a short amount of time. Can you think of the types of foods we want when we are comfort eating? (The group should respond with high fat / high sugar options). *When we are children we are often given food to cheer us up. If that happens time and time again then when a child feels sad or unhappy they will automatically want to eat comforting food. Trying to break this habit in adulthood can be very difficult. It is easiest if the link is not made to begin with."*

"Boredom is a really strong contributor to people overeating. You might notice yourself wanting to eat when you are bored. Many children are given food when they moan that they are bored because it provides a distraction and keeps them quiet. Again, trying not to give your child food when they complain they are bored will stop them making the link between boredom and eating."

"Can anyone relate to any of the internal triggers I have just spoken about? Can you think of examples of your child's unhealthy behaviour caused by any of these triggers?"

Allow the group to feedback. This time to reflect can be very useful. Keep an eye on the time though as there is still an activity to get through and some parents might have a lot to say on this topic!

Internal triggers activity

Divide the parents in to 4 groups and give each group a piece of flip-chart paper and flip-chart pens. Give each group one of the 4 internal triggers discussed and ask them to list their ideas of how they can manage or prevent the trigger. Provide assistance if necessary as this might be difficult for some parents. Ask the groups to feedback.

Example answers include:

- Hunger
  - Offer the child a healthy snack
  - Make sure meals are nutritious and healthy
  - Make sure meals are planned at certain times and your child knows when their next meal will be

- Cravings
  - Offer the child a healthy snack
  - Distract the child for 20 minutes until the craving has disappeared
  - Teach them the difference between hunger and cravings

- Unhelpful thoughts
  - Turn the child's negative thought into a positive one

Remind them of all the good things they have done
Look on the 'bright side'

- Negative feelings
  Help your child to talk through their feelings rather than eat through them
  Turn their feelings into a more positive way of looking at the situation
  Question why they are having or asking for food – talk through their feelings

Conclusion

"Well done. I hope you found both the activities useful. Today we have looked at both external and internal triggers and explored how to identify the triggers, how we can reduce these and how we can introduce healthy triggers in their place. Some of these changes might be small, and others might seem major for you. Either way, introducing these changes consistently is the key to them being introduced successfully. The new habits will soon become the norm and you will all have forgotten that you used to do things differently."

CHILDREN RETURN FROM THEIR EXERCISE SESSION

Re-cap and challenge setting

"Thank you all for coming along today. I hope you've all enjoyed it. Today we talked about how we need to think of food as a fuel for our bodies and we need to eat the right amount so we stay in balance. We also looked at the 5 food groups and why we need to eat a balanced diet. We also talked about the traffic light system of food and how the green foods are healthy for us so we want to eat more of these and we want to eat less of the red foods as they can make our bodies unhealthy. Try and use the traffic light system this week to choose the foods you are having."

"Remember we really want your feedback so feel free to write what you thought about today on the feedback sheet. You can put up things you enjoyed or found really useful. Changes you are going to make because of what we have talked about today. Or maybe something you didn't really understand or would like more information about."

"Next week the session is called 'Eat right, stay bright' and we are going to start taking a good look at the types and amounts of food you are eating and provide you with some really good advice about practical changes you can make."

"Lastly, I need to introduce your challenge for the week. (Hold up the Challenge Chart). *Week 3's challenge is to do 30 minutes of activity every day. I'm sure you will all do well at this and get your gold star. Any questions? OK, great. See you all here at the same time next week. Have a good week. Good bye."*